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DEPARTMENT OF TOXIC SUBSTANCES CONTROL

GREEN RIBBON SCIENCE PANEL

MEETING

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SIERRA HEARING ROOM

1001 I STREET

SACRAMENTO, CALIFORNIA

MONDAY, NOVEMBER 14, 2011

9:30 A.M.

EHLERT BUSINESS GROUP

(916) 851-5976

APPEARANCES

Green Ribbon Science Panel Members

William F. Carroll, PhD, Co-Chair

Ken Geiser, PhD, Co-Chair

Ann Blake, PhD

Jae Choi, PhD

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George P. Daston, PhD

Arthur T. Fong, PhD

Joseph Guth, PhD

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Richard Liroff, PhD

Timothy F. Malloy, JD

Roger McFadden, PhD

Kelly Moran, PhD

Oladele A. Ogunseitan, PhD

Robert Peoples, PhD

Julia Quint, PhD

Julie Schoenung, PhD

Megan R. Schwarzman, MD

Michael P. Wilson, PhD

Julie Zimmerman, PhD (via Webcast)

APPEARANCES

DTSC Staff

Deborah Raphael, Director

Odette Madriago, Chief Deputy Director

Kathryn Barwick

Colleen Heck, Senior Staff Counsel

Radhika Majhail

Jeffrey Wong, PhD

Also Present

Dawn Koepke
McHugh & Associates/Green Chemistry Alliance

Gene Livingston
Greenberg Traurig/American Cleaning Institute

Davis Baltz
Commonweal *and* CHANGE Coalition

D. Douglas Fratz
Consumer Specialty Products Association

Maia Jack, PhD (via webcast)
Grocery Manufacturers Association

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PROCEEDINGS

9:33 a.m.

CO-CHAIR GEISER: Good morning, all. Welcome to another beautiful day in Sacramento, a sparkling fall day. I was told when I got here that the fall in Sacramento is beautiful, although in Saturday I was in Maine, which is also beautiful, I might point out. But it's great to be here and it's great to see everyone and have you all here.

We have a very packed day and a half ahead of us. I think it's going to be a very productive one, it's an optimistic one, and I am pleased to open the meeting. Bill Carroll and I are thrilled to be here, of course, as usual.

I think, let's see. I am going to next turn this over to Radhika.

MS. MAJHAIL: Right here.

CO-CHAIR GEISER: And she will give us our opening and then we will hear from both the Department Director and the Secretary. Radhika.

MS. MAJHAIL: Thank you, Ken. Good morning, everyone. I welcome you all here at the Sierra Hearing Room today for the Green Ribbon Science Panel. I am Radhika Majhail. And I along with Veronica Villaseñor, Kathy Barwick and Marcus Simpson, who you met outside with DTSC, are here to assist you today and tomorrow.

Before we get started let's do the quick

housekeeping. Restrooms out the door on your left, past the Byron Sher Auditorium. Fire exits, there's a big door right behind me and the two doors right in there, those are our quick fire exits from here.

We have a cafe on the main floor so snacks and coffee are available for purchase from there. Also breaks. We will be announcing our breaks and lunch. There's a break session in the morning and a break session in the afternoon. We will be announcing those as we approach to that time. One thing I want the panel members to keep in mind. During the break session please remember the Bagley-Keene requirements in your mind.

For our online viewers, please email your comments to us at green.chemistry@dtsc.ca.gov. For comments please email green.chemistry@dtsc.ca.gov. And also keep in mind that there's a lag time behind, you know, between the actual happening events in the room and the webcast. So it would be really nice if you guys can send us your comments -- not even comments. Just send us an email with your intent to speak or the intent of submitting your comments so we can put your name in the queue. That way when you're ready with your comments, you know, we know that it's coming up.

Other than that, we're ready. I will turn it back to our Chairs, Bill Carroll and Ken Geiser. We'll do that after -- let me do the agenda review before we do that,

just, you know, one quick time.

After our welcome remarks and introductions we're going to do our informal discussion of -- we're going to present the -- have a presentation or talk from Odette on our product information draft regulations. After that we'll have public comment. Then we'll do the discussion session. We'll take a lunch break and we'll have discussion again after lunch. And that is pretty much, you know, the basic agenda for today.

So with that I hand it over back to Ken.

CO-CHAIR GEISER: Thank you and thank you for all your work in keeping us on public track, as it were.

Well, we are going to open here with some welcoming remarks and I think we are very pleased and honored to have the Secretary, Matt Rodriguez, here to open the session for us.

SECRETARY RODRIGUEZ: Well thank you very much. And actually it's me that is pleased and honored to greet you and welcome you to Sacramento and thank you for working with the state of California.

Looking at the membership of this panel the other day I was just tremendously impressed by the qualifications of everybody that is sitting at the table today. And also just tremendously impressed that so many of you would be willing to come in from all throughout the country to help

us out as we deal with a very, very difficult and significant issue confronting not only California but the country and the world and that is the introduction of chemicals into our everyday life where we don't know exactly what the ramifications of those actions are going to be.

It's a very, very difficult issue for us to deal with. But looking at the qualifications of the folks sitting here at the table I feel that this whole issue is in very, very capable hands. And as I said, I am just very, very appreciative of your willingness to give of your time and your expertise to help us out as we try to come up with a regulatory scheme to deal with this very significant issue.

I don't want to take too much of Director Raphael's thunder here but one of the things that she has said repeatedly is she has described her work on the regulations as it's very, very important that the regulations be meaningful, practical and legal defensible. And I think that reflects the priorities of this administration as well.

It's very important, it's a significant issue. But we want to make sure that whatever regulatory scheme we design here in California to deal with green chemistry issues is meaningful. Are we choosing the most significant chemicals to focus our resources on. And when we come up

with a regulatory scheme and we come up with recommendations or regulations resulting from this scheme is what we come up with, is it practical? Does it really help society? Does it really help to deal with the issues posed by the chemicals that are being introduced into our everyday lives?

Those are the kinds of questions that we need to ask as we develop this scheme. I think that the Director and the staff at DTSC has done a wonderful job in this most recent draft. I'd be very interested in your comments, however. I think a lot of progress has been made. But we're really interested in coming up with a program that will significantly help us to address the issues posed by green chemistry and the chemicals that we're introducing into our everyday lives.

And then being an attorney, having it be legally defensible is very important to me as well. And I think that having a panel such as this is so important to demonstrate that we've got a very, very sound scientific basis for whatever comes out of this group and whatever comes out of this process. It's important for us to be able to explain to the public and to the courts, if necessary, that we have considered the ramifications of these regulations, we've looked at them from a scientific basis, and that they make sense.

And let me just end by saying it's not only the

courts. But frankly, we live in a very difficult time in terms of the fact that it seems that there are segments of the population that will always question government decisions or government regulatory programs. Some folks will think that they're not going far enough, other folks will say that it's gone too far and we're stifling development, and it's very, very hard to find that balance.

A panel like this is so important in demonstrating to the public, not just to the courts but to the public and to all the stakeholders who are concerned with green chemistry issues that we are trying to really understand all the ramifications of the issues. That we are looking at the practical effects of our regulations and that we are making the bets attempt that we can to come up with a solid, well-reasoned regulatory program.

It's important to have transparency behind programs like this. It's important to be able to explain, particularly to an attorney such as me when I'm sitting with a bunch of scientists, in lay terms why it is what we're proposing, what we're doing and how it is we're going to be making decisions in these very, very difficult issues.

And I think that having a panel discussion such as you are going to have over the next two days is very, very important in achieving that goal of explaining why we're doing what we're doing and how we're going to make decisions

in the future.

So I'll just end by saying, again, that I truly appreciate the time you're putting into this. I think that in many ways we are setting a precedent for the rest of the country if not the world on how do you address issues such as this. And I am just pleased and honored to be a small part of this particular program, thank you.

CO-CHAIR GEISER: Thank you, Secretary. Now I would like to turn it over to the administrator of the Department, someone who knows us very well.

DIRECTOR RAPHAEL: Good morning, everyone. Good morning, Panel, good morning, folks who are in the room. Radhika, do we have more chairs that can come in? Are they coming?

MS. MAJHAIL: Yes.

DIRECTOR RAPHAEL: There's one chair. I just want to make sure people don't have to stand the whole, that could be very painful.

Okay. Well first of all, I am so grateful for one very wise decision that our Governor made and that was to give us Matt Rodriguez as Secretary of Cal/EPA. As you can tell, he is incredibly thoughtful and I have been so blessed with his guidance and his questioning. He is not a scientist. He comes to this with a very different perspective and asks the good questions and the good

discussion.

So I think you should all know that he has actually been very much briefed on this issue of green chemistry. He has been through many hours, actually, of discussion and I very much appreciate his engagement and his willingness to get down into the details as well as step back and ask the bigger policy decisions.

And I have also been incredibly grateful for the support of the Governor's Office. That is something that I witnessed before we released this informal draft. The Secretary and I and Odette went and briefed the Governor's staff and they also, as you would want them to do, asked very tough questions. At the end of it they were incredibly pleased. They felt that they understood what we were trying to do and they understood that we weren't finished.

And I think that's really the main message of today that is, you all know very well, it's not going to be a new message. These are informal regs. And the beauty of that is that we can have debate, we can have discussion. And so I would invite everyone in this room to take advantage of that.

For the next day and a half we are going to hear primarily from the expertise around the table here. That's not the only voices that influence or debate with us. Odette and I were in San Diego last week at a fabulous

conference organized by John Ulrich. John, where are you? Back there, yes. And Dawn Koepke. They did an amazing day-long panel on green chemistry down in San Diego with a lot of voices. People around this table were there as well as many industry colleagues. And it just gave me the sense that we are at the beginning of a very, very fruitful conversation.

I want to just talk about, spend a minute just telling you what I think is different this time, I hope, than last time around. And thanking you for your perseverance. You have all been with us for going on three years. This is an amazing journey that we have traveled.

I hope that what you see before you and that what you spent some time with looked clear. That at least you understood the problems we were trying to address and some of the solutions. Some of the solutions should not have been a surprise, they should look familiar. They were things that, many of them are things that came out of the discussion at previous Green Ribbon Science Panel meetings. And I hope you recognized your input throughout that document.

We wanted to make it more understandable. Not just to the, I like to say, the Tim Malloys who get great pleasure over a bag of potato chips and reading regulations. But to a broader audience that might be very interested in

the outcome but not have the stomach for 68 pages of text like that. And so Odette put together that 16 page summary. We put together cheat sheets, if you will. How is it different last time versus this time. We tried to pull out some of the significant policy decisions so that people from all aspects of this issue could relate to it and could, could give us feedback.

Because what I wanted to avoid and I'm hoping to avoid moving forward are the sound bites of distress. You know, where somebody reads something and then it gets repeated over and over again and gets escalated over and over again. For us to be successful we need to lower the emotional level of discourse and we need to take a look at what we're trying to do. 1879 was passed and adopted and signed by the Governor. This is our attempt at doing that practical, meaningful, legally defensible approach.

So today in the next -- so what I want to do right before I turn this over is have all the staff at DTSC who worked on this who aren't already standing, please stand up. And I mean my public participation people as well. And Michael, I don't know where you are. People behind me, stand up. Why is everybody sitting down? Just stand up. Come on, we want to go through this.

(DTSC staff stands.)

(Applause.)

DIRECTOR RAPHAEL: Thank you, thank you. Bob Doughton, stand up. Okay. Daphne. What are you -- all right, there's a lot of people who refuse to stand up. It shows how much power the director has. But okay, that's okay, I can deal with that. (Laughter.)

So my last thank you is to all of you. I imagine there were moments when you wondered if it was worth it. If you wondered if this thing would ever get off the ground. If you wondered, you know, were you even being listened to. And so I, with my deep gratitude I want to thank you all for coming here and being with us to the end. To our co-chairs who are just phenomenal human beings as well as scientists, I am incredibly grateful for your professionalism and your dedication so thank you very much.

CO-CHAIR GEISER: Thank you, Administrator. Bill and I would like to also welcome you. But before that I thought I might just take a moment to go around the room and just recognize for the Secretary, who doesn't know each of us by face, the people that are here. So I am going to ask people if they'll just share who they are and where they come from.

I will introduce Bill Carroll who is my terrific colleague up here. We make a good case for the Odd Couple I think. But Bill and I have done a great job at working together and helping to do this and I've really appreciated

having Bill as my co-chair here. But why don't we just start, I guess. Rich is going to be a little bit late here but I'm going to start with Roger. And just say who you are and where you're from.

PANEL MEMBER McFADDEN: Okay, thank you. I'm Roger McFadden, I'm senior scientist at Staples.

PANEL MEMBER BLAKE: Ann Blake, environmental and public health consulting.

PANEL MEMBER CORDS: I'm Bruce Cords, Three Seasons Consulting, representing Ecolab.

PANEL MEMBER DASTON: George Daston, Procter and Gamble, Cincinnati.

PANEL MEMBER WILSON: I'm Mike Wilson, the Director of the Labor Occupational Health program at UC Berkeley and associate director for integrative sciences of the Berkeley Center for Green Chemistry.

PANEL MEMBER CHOI: Thank you. This is Jae Choi from Avaya, Denver, Colorado. I'm responsible for product reliability globally.

PANEL MEMBER QUINT: I'm Julia Quint, I'm retired from the California Department of Public Health.

PANEL MEMBER FONG: I'm Art Fong, IBM Corporation.

PANEL MEMBER OGUNSEITAN: Oladele Ogunseitan, professor of public health and social ecology at UC Irvine.

PANEL MEMBER GUTH: Joe Guth, Science and

Environmental Health Network and also a research scientist at the Berkeley Center for Green Chemistry.

PANEL MEMBER MALLOY: Good morning. I'm Tim Malloy from UCLA Law School of Law.

PANEL MEMBER SCHOENUNG: Good morning. I'm Julia Schoenung, faculty in Chemical Engineering and Material Science at UC Davis.

PANEL MEMBER KIRSCHNER: I'm Mike Kirschner, president of Design Chain Associates in San Francisco.

PANEL MEMBER SCHWARZMAN: I'm Meg Schwarzman. I'm an environmental health researcher at UC Berkeley School of Public Health and also associate director for health and environment in the Berkeley Center for Green Chemistry,

PANEL MEMBER PEOPLES: Good morning, I'm Bob Peoples, I'm the director of the ACS, American Chemical Society, Green Chemistry Institute.

PANEL MEMBER JOHNSON: Dale Johnson, I'm from Emiliem, Inc. and UC Berkeley.

PANEL MEMBER MORAN: Good morning, I'm Kelly Moran, TDC Environmental.

MS. BARWICK: And as you know I'm Kathy Barwick, I am staff here at DTSC. For this meeting I am here representing Dr. Julie Zimmerman from Yale University. I'll be monitoring the mailbox and when she has comments I'll turn her card up and read those into the meeting.

DIRECTOR RAPHAEL: We really appreciate that.

CO-CHAIR CARROLL: And I'm Bill Carroll, Occidental Chemical Corporation in Dallas. And I just want to take a minute to thank Ken for his kind words and to return them in kind.

We have had, we have had kind of a journey as chairs as well and there's been a lot of time invested. But I have to say, it has been overwhelmingly pleasant both to work with the Panel itself but also with the Director, particularly the new director.

And I will simply say that for those of you who are wondering about the Odd Couple remark, I am simply going to leave it to you to decide who is Oscar and who is Felix.

(Laughter.)

CO-CHAIR GEISER: I can assure you that it's Bill's sense of humor that gets us through much.

And I just want to add my own thank you. We have been on this journey for well over three years I think at this point. We have had a whole series of meetings here in Sacramento. It's interesting to go around the room and just listen and watch each of because actually I've grown quite fond of you all. You have clearly devoted a great deal of attention and time and work to this effort.

I know at times when I have stepped back with Bill and said, what are we offering to make sure that they all

come every time. But you really have come every time and you really have done the hard work of making this panel really be an outstanding science panel. You have offered your wisdom, you have offered your intellectual contribution, you have offered sometimes your policy or political opinion. You have offered the things that really make a panel really work.

And you have also listened to each other and you have built upon one another. One of the thing that I always find valuable in a longer term panel like this is that in the early period people just kind of speak from their own particular knowledge and their own particular discipline, their own particular position. But as time goes on, if we're lucky, a panel begins to build off of each other. Recognizing the differences amongst us but also taking the time to really think about what someone says and how to add to it to be constructive or to engage it in a way that differs from it but adds to it by enriching it with a different view.

And I think what is very good about this panel is that we have really achieved that level of success. And so I just -- it is kind of just a salute to you. That you really have worked well, not only as individuals but more so as a collective. As a voice of science and as a voice of a really thoughtful contribution to the state of California

and so I really thank you for that.

Okay, so with that -- oh wait, I can't remember whether Radhika said this. Cell phones, did she say something about cell phones? Okay. Please turn your cell phones off or put them on mute. It's like being at a symphony, you know. We don't want to be interrupted by a buzz.

With that, we have a big agenda ahead of us. We are going to spend today and tomorrow going through the questions that Odette has sent out to us to look at this document. think we all recognize that the document is a more streamlined version, it is a shortened version. It's a version that clearly took into account a lot of the contributions not only of the panel but also of many others who offered their advice and comments during this time.

There's going to be room for some general comments about the entire document but we have been asked to focus on three specific areas where the Department thought that our contribution would be most significant. We're going to spend today and tomorrow -- today on the first two of these and then tomorrow n the last one of these. At the end of it we will also have time for general comments.

Some of you will only be here for today and so what we're going to do is offer a little time at the end of the day just to make sure that if you have any comments

about the topics that may come up on our second day that you want to provide. I know this is -- Mike, I think you're one of those who will not be with us tomorrow. So please, if yo have comments, offer them at that time.

So I think the first thing to do is to get a general overview of what has been sent to us, this new draft and to take a look at sort of its flow, the construction of it, how it is similar to certainly the legal mandate but also how it differs from some past drafts. And what important issues came up as the staff really wrestled with trying to come up -- sometimes with compromises, sometimes with a clever way of handling a difficult situation. But always, I think, constructively.

And I'm going to turn this over to Odette. She, as you know, has been just a terrific work person in really making this happen. You know, as I have grown to know Odette and seen the kind of serious, stable, thoughtful way she handles things it's just been, I've been very impressed by her competence and capacity. So thank you. Odette, please tell us what we've got in front of us.

CHIEF DEPUTY DIRECTOR MADRIAGO: Thank you for your kind words, Ken. And I wanted to start by echoing what Director Raphael, Debbie, and our co-chairs have, same in saying, thank you to all of you. First of all, thank you for your incredible work this year. It really has been very

beneficial in crafting this latest draft of the regulations and I hope you've seen that in that and we'll talk about that a little bit as I go through the review this morning.

And I also wanted to echo something that Debbie said. I want to thank you for your patience in working with us and sticking with us through some rough growing pains. I think last year was kind of frustrating for many of you as it was for us in terms of getting the most valuable input from you. And this year with your help and the help of your chairs we came up with a different format that I think has been incredibly beneficial in terms of maximizing the use of your time and your expertise in advising us. So I just want to offer my personal thanks.

I also want to thank the team, which are kind of spread out. A number of them are sitting back there. And our esteemed attorney, who is going to have to join me at the table or join the others; at some point I'm sure she'll have to answer questions.

And we did -- Debbie I think has shared with you in the past we had some incredibly wonderful consultants working with us. Two of them are -- I see Michael DeBartolomeis from the Department of Public Health and Melanie Marty from OEHHA. They helped us with the scientifically meaningful and practical aspects. And then also Claudia Polksky from the Attorney General's Office

really helped us, working with Colleen, the two of them, on the legally defensible aspect. Claudia, unfortunately, could not be with us today, she is involved in some long litigation and she had another hurdle thrown her way this morning. So thank you to all of you too.

So this morning, as Ken has indicated, I am going to be reviewing the current draft of the regulations. As Debbie says, they're an informal draft. I am not going to go through the entire regulations. I am going to focus in some detail on those aspects of the regulations that relate to the discussions we had with all of you in May and July because I think that's most beneficial to you. And I also think I want to make sure you know the decisions we made after the discussions we had with you.

And then I will go over the three questions that we are particularly asking you to provide us input on. You know, we could have chosen at least several others but in the interest of time we knew we had to narrow it down. We figured three was the most we could, we could tackle and these three are the ones where we felt it would be most beneficial for us to hear from you. And you co-chairs will make sure that you do have time for a general discussion where you can, you know, talk about, comment on any aspect of the regulations that you'd like to do so.

So before I begin I would just like to go over the

handouts that you have. Hopefully we'll all have these. First of all there's two brand new flow charts this year, which I'll go over briefly. These replace the somewhat more complicated and psychedelic flow chart from last year. So hopefully these are a little more user friendly and I will be referencing them in a moment.

You have a document entitled Significant Changes, a two page document that highlights the most significant changes from the November 2010 draft to this draft. Obviously there's a lot more changes but those are the significant ones.

Then you have the 16 page summary document. Sort of like a Cliff Notes version. And on the back of that is a summary of the key time frames that are in the regulations to kind of give you a sense as to how long it will take to get through each stage of the process.

And you should also have -- let's see, those were on the left hand side. On the right hand side behind the agenda you will have the Questions for Discussion, which I'll be going over a little bit later. Attached to that there are two attachments which are just the details from the regulations that are the subject of those questions.

And then you have this document entitled Chemicals of Concern Identification, which I'll be referencing. And this relates to the lists that we're using to establish the

first list of chemicals of concern. And I'll reference that in a bit. So I just want to make sure everybody has got those handouts handy.

So I'm going to start by just briefly going through the two flow charts. This flow chart of circles, this is our concept--thanks to our graphic artists, I don't know if they're in the room today--of the kind of high-level, bird'seye view of the process in terms of how we're going to get from this huge universe of chemicals -- we've put down here "over 100,000," I've been told it's not quite that many. Whatever the number is, it's really big. So we've got to get down to very small product chemical combinations that we can really focus on for alternatives assessments.

So the first step will be the identification of chemicals of concern. The process set out in these regulations will initially be somewhere around 3,000 chemicals of concern. Then what we want to look at are products that have those chemicals of concern and get a very narrow focus.

Because that's all really that we, and I think manufacturers and other stakeholders, can afford to focus on, especially during the first stage of implementing this program. It's a brand new program, it will be kind of like a pilot. And to get it right we need to start out small.

And we do have limited resources, as we have told you many times and I think everybody gets that now.

So you will see in this magnifying glass here what we like to call the handful of product chemical combinations that we will ultimately be listing as the first priority products. And as you know by now, priority products are those products for which manufacturers will be required to do alternatives assessments. And then DTSC will look at those and assign regulatory responses as necessary for the selected alternative and/or the existing priority product if it's going to stay in the marketplace.

And I want to be really clear. When I say a handful of products I'm talking about very specific product chemical combinations. We're not talking about something like cleaning products or toys. We are talking about nail polish with formaldehyde in it or teething rings with BPA in it. I don't know if they BPA in teething rings but anyway. That's the kind of very specific product chemical combination we're going to be listing as priority products so I should put that in context.

So very quickly. The next chart that you have, a tad bit weedier but not too much. And it shows the process we're looking at. Starting out with looking at chemicals to come up with a chemicals of concern list.

The box in the middle there highlights what we're

going to be looking at. Which I'll go over as I'm talking in more detail but this is just a handy reference guide. Then we're looking at product chemical combinations. Obviously products that contain chemicals of concern to get to the priority products list. And again, this is a cheat sheet of the key factors that we will be looking at to come up with that list.

And then we have alternatives assessment, which gets to alternative selection and then regulatory responses.

So again, this is still very high level but we thought it was better this year to provide something a little less weedy and a little easier to go through quickly. Hopefully they have been helpful and we do accept comments on any improvements that we can provide you in our guidance documents.

So with that let's start digging deep. And I've kind of, I've organized this along the four topic lines that we discussed in our meetings in May and July. We started out by discussing the process for prioritizing chemicals and products; we talked about the de minimis exemption. And in our second meeting we talked about the alternatives assessment process and how to provide quality assurance for alternatives assessment. So those are the four areas that I'm going to focus on this morning.

So chemical/product prioritization. As I

referenced, we're going to start out with an initial list of chemicals of concern. The regulations themselves will actually establish this list. It will be a robust list of approximately 3,000. We're still trying to refine that before we give it an exact, precise number because we have to eliminate duplicates and eliminate those things exempted by statute.

As you probably know and if you have taken a look at the materials, this initial list will be established by saying that any chemical that is on one of 22 existing authoritative body lists is a chemical of concern for the regulations.

All of the source lists which are listed in that handout I referenced earlier, these are -- the lists themselves or the body that created the list, they all meet the OEHHA definition of authoritative organization and/or they meet the DTSC definition in these regulations of reliable information. Some of these being reliable information that demonstrates the actual occurrence or potential occurrence of exposure. These lists are widely recognized nationally and internationally and they have been used to initiate actions to protect public health and/or the environment.

We've received a number of questions from folks, well, how did you go about choosing these lists, these 22

lists? And this is, indeed, something we want to have a conversation with you about. But those were the general high-level criteria that we used to come up with this list of 22 source lists to establish the first list of chemicals of concern. In the list that you have there's a column that shows for each of these 22 lists the types of hazard traits that are exhibited by chemicals listed on those lists.

So why did we decide to take this first approach for the initial list of chemicals of concern. And I do want to point out that as I'm going through this, for a lot of it I'm going to try to give you some of this explanation of why. Probably not for every little decision just in the interest of time but some of it I think is important for you to know the why behind our decision.

So we believe that this approach will send immediate signals to the marketplace. And my marketplace I mean manufacturers, distributors, retailers and consumers. Saying, these are all the chemicals that not just DTSC but other authoritative bodies have flagged as being of potential concern.

This approach also enables DTSC once the regulations are adopted to immediately begin work on identifying the product chemical combinations to list as priority products. This is one place in the regulations where we think we have created a real time saver that will

allow this process to move forward more quickly to alternatives assessments and ultimately regulatory responses.

Number three. We heard a lot of concern. We discussed it around this table, we've discussed it internally, we've discussed it with stakeholders, that the prior approach where we had a relatively small list of chemicals of concern was likely to lead to early, oftentimes regrettable substitutions. Because with a very small list of chemicals of concern, we felt that for some manufacturers at least, there would be the incentive to, let's get out of that list. We don't want to be drawn to DTSC's attention and have our product listed as a priority product. So we're just going to get chemicals of concern out of that.

That would have been in some cases, not all cases but in some cases, relatively easy to do if you only had a small number of chemicals of concern that you needed to avoid. And you might jump to -- there are many other chemicals you could jump to, some of which we might later on add on to our chemicals of concern list as we went to expand it. So our thinking is that by starting out with a very robust list of chemicals that have already been identified by somebody else as being a potential concern, that there will be less of an incentive for these early, potentially regrettable substitutions. Something you may want to talk

with us about today.

Also, you know, one of the things we thought about is we went back and looked at AB 1879, our fundamental, underlying statute which specifically instructs us to use chemical prioritization information already developed by other authoritative bodies to the maximum extent we can do that to minimize the state's costs and maximize our benefit. So we think that is in keeping with that directive from the statute.

And finally -- actually I have two more points here I want to make. This is a bit long but I think it's important and because we've gotten a lot of questions on this approach. I really want to share with you all of our thinking. So of the four steps that are laid out in these regulations the chemical identification and prioritization is the one step that's already really been very robustly addressed by many other authoritative bodies.

So we felt, you know, duplicating that work or rethinking that work maybe is not the best use of DTSC's limited resources. So let's come up with a process where we can focus our resources on those things that are really unique and ground breaking about AB 1879 and these regulations. And that's coming up with that list of product chemical combinations for which alternatives assessment and regulatory responses will be required.

Now yes, there are a few other states and programs that are identifying products for special regulation but in most cases those are very narrow in what they can look at. And the purpose of identifying those products is very different from the purpose we're looking at, which is to require alternatives assessments. Something that no one else is doing. So we think this process enables us to do that.

And finally, in our discussions with various stakeholders what we have learned is that there are some industry associations and retailers out there who are already beginning to develop their own lists of chemicals of concern, though they may have other names for them, that they are using to screen the products they purchase from their suppliers so that they don't get upstream products that contain chemicals of concern. And a number of these lists that folks have shared with us, they are equally robust as the lists that we are talking about coming up with here.

So those are why we have, you know, preliminarily we think this is a pretty good approach. I will say this is one of the three things that we are specifically asking for your input on today.

So I do want to point out, you know, after we've got this initial list going and we're going on our priority

product list, the regulations do enable the Department to add to that list. Any additions to the list of chemicals of concern will be done using a public review and comment process.

And the regulations set out narrative criteria for adding to the list. They are the kinds of criteria that, you know, we have discussed with you. You know, the potential for adverse public health and environmental impacts, with special consideration on sensitive sub-populations and environmental habitats. Potential for exposures, availability of reliable information to substantiate these exposures and adverse impacts, as well as the availability of safer, acceptable alternative chemicals.

In terms of what we mean when we talk about adverse impacts. The definitions in the regulations provide those lists if you want to get down into the weeds. Which we can certainly do so later today if you wish to do so. But I am going to move us along now to priority products.

So once the regulations become effective, if not before, DTSC will immediately begin work on identifying the handful product chemical combinations that will be first listed as priority products for which alternatives assessments will be required. This list will be established using a public review and comment process. The regulations would require that the first proposed list be released for

public review and comment within six months after the regulations are adopted. Again, another somewhat fast track. We're not achieving the fast track that a lot of people would have dreamed of but we're trying to speed it up as much as we think we can and still keep these practical and meaningful. And legally defensible, I might add.

So the approach we have taken to prioritizing priority products: We are using narrative criteria. As you know we had a lot of discussion around this table about using narrative criteria versus using a more weighted or structured approach. And again, this is one of the three things we are asking you to comment on today.

So the criteria that we have come up with we think are pretty robust and they are the kind of criteria that we have talked with all of you about and heard comments on. Again, because we are looking at a product chemical combination we are going to be considering the potential adverse impacts associated with the chemical of concern in the product. Again, with special consideration given to sensitive sub-populations and environmental habitats.

We're looking at potential exposures to the chemicals of concern in the product. And here we'll get things like market presence information, reliable information indicating there have been exposures or possible exposures, information concerning the household presence and

use of the product and similar products with similar chemicals of concern.

And the potential for public or environmental exposures throughout the life cycle of the product. And here we are really focusing deep on the use -- who is using the product, for what purpose are they using it and how is it being actually applied. We are looking at the availability of reliable information to substantiate potential adverse impacts and exposures. And I want to provide some clarification here because we have gotten questions.

When we say availability of information is a factor in listing a chemical or listing a product chemical combination, we are not taking the approach, as some people have suggested, that we should give priority to something that lacks information. That's not the decision we've made here. The decision we've made is that we are going to feel more certain about listing something if there is reliable information to substantiate potential adverse impacts and exposures.

We are going to be looking at other federal and California regulatory programs to see if they are already addressing some of the potential adverse impacts and exposure pathways that we would be concerned about. To the extent that a product chemical combination is already being

significantly addressed by other programs, that might weigh into our thinking in terms of whether or not we want to attack it, or do we want to attack something that really isn't very much addressed at all? It's all part of prioritization.

And then in addition to those factors, the regulations would give DTSC the discretion to consider in the prioritization process whether or not there is already an existing, safer alternative out there on the market. This is something we have discussed around this table. It's also something that has come up in discussions with some of the industry associations we have talked to since we last saw all of you. And at least several of them have indicated, you know, all of us, we're doing the right thing, we've got those nasty chemicals out of our products. But there's these other off-brands out there that, you know, are undercutting us and giving us a bad name. We'd welcome it if you would get them to come up to this bar or, you know, take the products off the market. So, I mean, we've heard it from several different sources that this is something that we should consider.

We have also in the regulation identified five key prioritization factors, which we say, after we have come up with some preliminary thoughts on what should be priority products, let's go back and look and make sure that we're

giving particular attention to these five key factors.

So looking at the COCs that pose a significant potential to cause adverse impacts, products that are widely distributed, widely used, a significant potential for release of the COC, the quantities that can result in adverse impacts.

And then we're looking at the actual types of potential exposure depending on the type of product. So for assembled products, giving special consideration where there's a potential for exposures to the COC through inhalation or dermal contact. And for formulated products, whether or not the product is intended to be applied directly to the body, dispersed as an aerosol or a vapor, or applied to hard surfaces with the likelihood of runoff or volatilization. Again, some of these were ideas that we got talking with all of you.

So the big question is, why are we using the narrative standard rather than a weighted or other more structured standard? Because that's something there has been quite a bit of debate about in this room and elsewhere.

So the bottom line I think for us, at least for me is, you know, one of our big objectives with this regulation is to adopt a forward looking regulation that can be applied to a variety of product types and that can take advantage of scientific and technological advances and improvements over

time. And we debated this quite a bit internally, as Debbie will tell you.

And I want to tell you that -- I don't know if we recognized all -- Debbie did. Besides our regulations team and our external consultants we also this time have an implementation team, which are the folks that they come from the program that ultimately is going to be responsible for implementing these regulations when they become effective. And so we've been getting a lot of practical input from them and involving them in the discussions on, you know, is this doable. And is there total consensus around that table? No, but I think at least at the end of those discussions, you know, we feel pretty good about the policy decisions that we have been making.

So in terms of this objective of having a forward looking regulation. Basically, bottom line, I think we really felt that using this narrative standard approach is the only approach that is truly going to meet that objective. You start using weighted approaches or structured approaches and you've locked yourself in to something that can't grow with time and by its nature is going to require you to come back and spend time rewriting the regulations to make them meaningful and practical and legally defensible as we go forward.

And I can tell you that the regulatory team

members and our scientific consultants all strongly supported this approach from the scientifically meaningful and practical standpoint. And our legal advisors, both our DTSC counsel who is still sitting in the audience I see, as well as our attorney general consultant, they also strongly supported this. They viewed it as both legally advisable and legally defensible.

So finally I want to make sure that you understand that one of the approaches that we talked about here that we really liked, you don't see in here because it turns out it wasn't really legally defensible. And that was the approach of trying to speed this up even further by calling out specific product chemical combinations in the regulations. So you won't see that in there and that's why. It's just not legally doable.

Okay, so de minimis exemption. Now this is one that we discussed quite a bit here; it is not one that we're focusing our three questions on. But certainly if there's something you want to talk about we can do it during the general discussion. So the approach we have taken is for defining the de minimis level. And just to put context to this, the significance of the de minimis level is, if a priority product has the chemicals of concern at less than the de minimis level then an alternatives assessment is not required for the priority product. That is the sole

significance of the de minimis level; except that also when you get to regulatory responses it's pulled in there a little bit as well. But primarily it determines whether or not an AA is required.

So the default level that we set up in the regulation is actually a two-tiered default level. It's .01 percent by weight for chemicals exhibiting one of nine specified hazard traits or end points. These are bioaccumulation, carcinogenicity, developmental toxicity, endocrine toxicity, genotoxicity, immunotoxicity, neurotoxicity, persistence and reproductive toxicity. For chemicals that don't exhibit any of these nine traits or end points the default de minimis level is .1 percent by weight.

We have also included in the regulations a provision allowing DTSC to set a higher or lower de minimis concentration level and we would do this on a product chemical-specific basis and we would specify it as part of the priority product listing process.

So this is where I wanted to very quickly talk about some of the whys for why we selected this approach. The lower .01 percent provides a ten-fold safety factor for chemicals for hazard traits that our scientists considered to be of high concern.

But what these regulations also do is they allow us to specify different levels, either higher or lower,

where circumstances warrant a higher or lower de minimis level. And this was something we heard a lot of suggestions from I think around this table as well as from our discussions with stakeholders.

Now I do want to point out here that, you know, as you can imagine, we have been urged by a number of people to use the .1 percent level that's used by REACH and many others and call it a day there. And we discussed that. That was certainly something that was on the table, you know, when we had our internal discussion.

But we looked at how these programs used this and primarily this level is used by these programs to determine when a reporting or labeling requirement should apply. In these programs, a concentration below .1 percent did not necessarily mean that that was a safe level.

So then we looked at how our regulations differ in purpose from these other regulatory programs. These regulations use the de minimis level to determine if there's sufficient concern to warrant to requiring an alternatives assessment and possibly regulatory responses. And because of the different purpose of the de minimis level in these regulations, versus how it's used in other programs, we felt it warranted consideration and in fact we actually adopted using a somewhat different approach. So that's our why.

I do want to point out that you will not see in

these regulations the terms "intentionally added" and "unintentionally added" chemicals. So we have not made a distinction between those two. However, if you look at the portion of the regulations that identifies the factors that DTSC would consider in setting a higher de minimis level than the defaults, you notice that what we would be looking at is the source of the chemicals of concern. And the sources that are called out there are the sources that are typically considered to be that that introduce unintentionally added chemicals. So from that standpoint there is still consideration to the concerns that surround unintentionally added chemicals.

We have applied the de minimis level, as we talked about many times, to the entire product when it's a formulated product. If it's an assembled product we were applying it to the component that is the focus of the alternatives assessment. And this would be called out when we list a product chemical combination on the priority product list.

And the process for the de minimis exemption, it is self-implementing but it does require a notification with specified information to DTSC.

So moving right along, we're jumping into the alternatives assessment process. It's essentially, I guess you could call it, a three step process. Once we list a

product chemical combination on the priority product list, any manufacturer that has a product of that nature needs to send us a notification so we know who to keep track of and who we can expect to receive alternatives assessment reports from.

We then split the AA process into what we're calling Stage I and Stage II. So after Stage I a preliminary alternatives assessment report would be submitted to DTSC. After Stage II a final AA report would be submitted.

So what's in Stage I of the AA? It includes four steps. The first step is identification of the product requirements. The function, performance, technical and legal requirements associated with the product and the role that the chemical of concern plays in meeting those requirements. And we ask the manufacturer to ask the question, make the determination as to whether or not a chemical of concern or a substitute chemical is actually necessary for purposes of the product requirements.

In Step 2 we ask the manufacturer to identify alternatives for consideration to meet the requirements of the priority product that have been identified and to eliminate or reduce the concentration of the chemical of concern or reduce the potential for exposure. And this includes looking at any existing alternatives that may

already be out there.

Step 3 is the actual comparison of the chemical of concern and potential alternative chemicals for potential adverse impacts. And here this is not looking at the full (A)-(M) factors, this is just looking at the chemical of concern and potential alternative chemicals for public health, environmental adverse impacts. Following those three steps then the manufacturer submits a preliminary AA report to DTSC with a work plan and implementation time frame for Stage II.

So what's included in Stage II? Stage II starts out with an identification of factors relevant for comparison of the alternatives. As you may recall we spent a lot of time talking around this table about how do we not make the alternatives assessment process overly burdensome and too lengthy in time, given the list of (A)-(M) factors in the statute that all alternatives have to take into consideration in some manner?

So we asked the manufacturer to go through a process of first determining which of the (A)-(M) factors, which exposure pathways, which life cycle segments are actually relevant to comparing the alternative or to comparing the priority product and the alternatives being considered. And we specified kind of a definition for deciding whether or not something is relevant. And, quite

frankly, this definition comes right from the discussions around this table. So we say that it's relevant if it would constitute both a demonstrable contribution to the adverse impacts of the priority product and one or more of the alternatives; and a demonstrable difference between two or more alternatives being considered, including the priority product itself.

So after identifying the relevant factors, exposure pathways and life cycle segments then the manufacturer actually does the comparison. Compares the priority product with the alternatives using available quantitative information, supplemented by available qualitative information analysis. And I'm going to come back to that phrase in a little bit.

After they have done the comparison then they make their alternative selection decision, which can be selecting one of the alternatives to develop and place in the marketplace or they may decide to retain the existing priority product.

The alternatives assessment that -- let me back up. The manufacturer can choose to use an alternative approach for doing their alternatives assessment. We wanted to provide flexibility here. We wanted to provide a pathway, a process that a manufacturer could look at and say, okay, I get it. If I go through these steps that's

what the regulations are asking me to do. And we set that out, we think.

At the same time we know that there are others who have a different process, who discover another process that they think works better for them. We want them to be able to use that, as long as at the end of the day they end up considering the same factors. Because that's the important part of the alternatives assessment, to identify alternatives and you make sure you consider the relevant factors, pathways and life cycle segments. So if they want to use an alternative approach they would submit a work plan to DTSC then they'd go about doing their alternatives assessment.

The rest of the process is like it was before. We review the reports, we ask for more information if we need it, and then we go into the regulatory response process. So pretty much the same as before with one exception that I'm going to mention.

So a couple of other features about the alternatives assessment portion of the regulations I'm just going to call out. One, it does require the Department to develop guidance materials before we list priority products. This is really important because these regulations themselves only go so deep and I think only should go so deep. Again, because we need them to be flexible, apply to

a variety of products and be forward looking. So the real down in the dirt, weedy details are going to be in those guidance materials, which we will be working with a number of public/private partners to develop. And those will be available on our website, of course.

The second feature I wanted to mention without going into a lot of details but we have worked to tighten up time frames where we can. And again, on the back page of that 16 page summary is kind of the summary of the time frames.

So the third thing I want to mention is information gaps. The regulations don't require manufacturers to fill the information gaps during the alternatives assessment process. That's why we say, do this using available quantitative information, supplemented by available, qualitative information.

The regulations do require as part of the AA process that the manufacturer identify information gaps. And then the regulatory response part of the regulations has been tweaked a little bit to specifically call out that DTSC can and will require information gaps if it determines they are necessary to be filled as a regulatory response, along with any other regulatory response that might be selected.

So this was something that it actually didn't come to our focus until fairly late in our discussions about

policy decisions in the regulations. And when it did it's something we gave a lot of thought and a lot of discussion to. And what we realized is, you know, we were hearing a lot of anxiety from stakeholders about the length of OEHHA's list of hazard traits.

And when we talked about and thought why is that causing the manufacturers such anxiety we realized that one of the big reasons is that the way the regulations had previously been written it could clearly be interpreted that manufacturers would have to fill all the data gaps for all of those 40-odd hazard traits for all priority products in all alternatives assessments.

That obviously would be very costly and very time consuming, not necessarily the best use of manufacturers resources, but it would drag out this AA process considerably. It would significantly delay how long it would take to get to the point where we could do regulatory responses and to get to the point where we would have safer alternatives on the marketplace.

(Panel Member Liroff entered the meeting room.)

CHIEF DEPUTY DIRECTOR MADRIAGO: Richard, right up here.

So we chose this pathway as being a pathway that we think moves this process forward and at the same time enables DTSC to require the generation of new data to fill

data gaps where DTSC feels that it's necessary.

So I want to close my discussion on the AAs by quoting Debbie, if she doesn't mind. Not her exact words but something that she starts all of her presentations on. I'm surprised she didn't start it today, I was prepared for her to do it. The regulations require manufacturers to ask the question, is it necessary to use a chemical of concern or a substitute chemical in the product? So they mandate the question. They do not mandate the answer. The manufacturers will still have the ability to make the decision once they complete the AA. It is their decision to make. We are not going to dictate that decision. However, you know, there are potential consequences for that decision in the form of regulatory responses. So that's kind of the framework we're viewing the AA through.

So I'm almost at the end here, folks. I'm not sure how I'm doing time-wise but I'll move it along.

So the last segment here, the quality assurance for alternatives assessment. We talked about, a lot about this before and it is the third topic that we are specifically asking you to discuss during the meeting.

So we are using a three prong approach to ensuring quality for the alternatives assessments. The one thing you will not see in here is a requirement for third-party verification. And a lot of that is because some of the

concerns we heard, some of them expressed in this room, about how much value that added.

So the three prongs that we are using is the regulations establish a certified assessor program, modeled somewhat on similar programs such as the LEED assessor program. We envisioned that having certified assessors that oversee the conduct of the AAs and the AA reports will hopefully ensure a better quality report when it comes in to DTSC. That will make much better use of DTSC's limited time in reviewing the alternatives assessments and conducting audits.

The second prong, which we have always said we would do, is the non-redacted portions of the alternatives assessments will be posted on the website for everyone to look at. We really won't know until we roll this program out how much redactions there's going to be in there and how much this will or won't help. We're going to have to see.

The third prong is DTSC audits. We have always said that we can and will do audits. What's different now is that because we are saying, we are going to focus on a very small handful of priority products, we now think that we will be able to do audits on a much larger percentage of the alternatives assessments we'll be getting, and we'll be able to conduct more in-depth audits than we previously were envisioning. So I think our audit function will be much

more robust and meaningful in terms of ensuring quality for the alternatives assessments.

And the why for this is we felt this was the best approach given our limited resources and given the feedback we were getting about the potential lack of value of third-party verification. But again this is something that we really want you to talk about today.

So now I am going to very quickly go over the three questions and then turn this back over to Ken. So if you can turn to this handout you have in your package that says Questions for Discussion. This is what you probably want to keep in front of you for the rest of the meeting. The first page goes over, sets a little context, most of which I've pretty much gone over, for the questions. And the rest are the attachments, which are just excerpts from the regulations that are pertinent to the questions asked.

So the first question concerns the chemical of concern list, the initial chemical of concern list. Which as I have already discussed we're developing it by using 22 existing authoritative body lists and I have already discussed our reasons for doing so. So our questions to you are: Are these the right lists to use as source lists? Is the scoping right? Should we be using fewer lists or more lists? And what we'd really like to know too is, are there unforeseen consequences to this approach? Something we

haven't thought about that we might want to consider in, you know, changing, augmenting this approach. That's question number one.

Question number two deals with the prioritization of products. And again we're talking product chemical combinations. And as I discussed with you, we have chosen to go with the narrative approach. We know there are a number of folks who would like to see a more structured approach. And a lot of folks who were asking for a more structured approach would like to see more certainty in that process. So our question for you on this topic is: What steps might be included to structure the prioritization process so that manufacturers are better able to predict the likelihood of their products being listed as priority products?

And in answering that question I'd also like you to keep in mind the reasons that I went over with you earlier in terms of our reasoning for going with the narrative approach and what some of the objectives we have that we would like to get out of this and is there a way to meet all of those objectives?

Thirdly, as I mentioned, we'd like you to discuss our approach to quality assurance for the alternatives assessments. And the questions here are: Given DTSC's limited resources, is this approach sufficient to provide

meaningful quality assurance? And second, what steps could we take to restructure or supplement this approach?

And thank you for listening to me and thank you, Debbie. So I am going to turn this back over to Ken and now I get to sit and listen, I guess answer a few questions. I will say, if you have legal questions Colleen is here and if you have questions about the lists or other science questions we have got a few folks sitting up behind me there who will be fielding those questions. So, Ken.

CO-CHAIR GEISER: Thank you, Odette. So we have about 15 minutes for clarifying questions. Again let me remind the GRSP members that this is not a time for discussion, this is for specific questions about what Odette has presented that you may not understand. And we'll take cards. I see Julie; let's start with you.

PANEL MEMBER SCHOENUNG: I'd like to thank Odette on behalf of everyone here probably, very nice work and a very nice summary of the highlights.

My clarifying question is just, what does it mean to be an informal regulation?

CHIEF DEPUTY DIRECTOR MADRIAGO: Okay. This is really a legal issue so Colleen is going to take it.

MS. HECK: Good morning. Essentially what it means is we are not operating under the rules of the Administrative Procedure Act, which is a very constraining

and very prescriptive set of rules that an agency must comply with in adopting regulations. It has very express procedures and time frames and rules of governance. We haven't invoked that process.

We want to do all of this up-front work, get as much information as we can. So that when we do initiate that process we have as good as product as possible as our starting point. So it means we don't have a clock ticking and we don't have a formal obligation to respond to comments, to prepare elaborate documents describing the regulations. That will come soon enough.

PANEL MEMBER SCHOENUNG: Thank you.

CO-CHAIR GEISER: Just a comment. Kathy has asked me to note that if you are not a member of the GRSP and are planning to make a public comment after the break you might want to take one of the cards that Radhika has here. Thank you. So now I have Joe, George and Kelly.

PANEL MEMBER GUTH: Well this is a very specific question. Odette, you described identification of priority products as being specific. Like you used an example, teething rings with BPA. So do you mean that the identification of products will be, will identify a product type and a specific COC? Or would it be teething rings and that would include teething rings that have any COC?

CHIEF DEPUTY DIRECTOR MADRIAGO: No, it will be

teething rings containing one or more specific COCs.

PANEL MEMBER GUTH: But you'll specify --

CHIEF DEPUTY DIRECTOR MADRIAGO: Yes, we will specify which COCs we mean when we list the product chemical combinations.

PANEL MEMBER GUTH: So if there are teething rings which have other COCs that are not in your list, they won't be priority products.

CHIEF DEPUTY DIRECTOR MADRIAGO: Correct.

CO-CHAIR GEISER: George.

PANEL MEMBER DASTON: Well I just want to add my thanks to Julie's. Obviously we have been doing this for three years and you have done, I think, a really good job of navigating, you know, a variety of opinions and trying to come up with something that is pragmatic and good for public health. That's not to say I am not going to have a lot of questions and comments as we go on but, you know, thank you for listening to the various opinions.

I just have a couple of clarifying questions for right now and one is, you know, in terms of these alternatives assessments. Basically you're going to get what you get from the manufacturers in terms of the alternatives and how do you identify whether they've really covered the universe of possible alternatives? Is it just going to be kind of a comparison exercise or is there

something more that is going to be done to suggest various alternatives?

And then the second is, and the process again starts with this listing of product chemical combinations. How is it, how are you going to get at the question of the small manufacturers that you expressed concern -- the industry groups that expressed concern as being the, you know, the real issues for some of these things. How are you going to make sure that you've identified all of them such that they are even participating in the program?

CHIEF DEPUTY DIRECTOR MADRIAGO: Okay, good questions. So the first question in terms of, you know, evaluating the scope of alternatives that a manufacturer chooses to evaluate in the alternatives assessment. I guess it's a two part answer. One is that it really is their choice. However, we do require -- if there is an existing alternative that we're aware of and we put it on our website they are required to evaluate that.

And the other part of the answer is, I believe, the guidance documents. As we start developing these guidance documents -- and I see them evolving over time and perhaps each document will focus in on different product types. And I see that a place where as we learn, that we can provide guidance and suggestions on the breadth and types of alternatives that a manufacturer for a given type

of product might want to consider. This is something perhaps -- you know, it's a really good question and certainly something that input will be welcome and appreciated.

So as to your second point about the little companies out there. And some of them may actually not be so little. Some of them will be little, yes. Some of them may be large but, let's face it, a lot of them are going to be out of country, which I think is probably why you're asking how are we going to get to them.

So what you're really talking about is how are we going to ensure compliance? And again I think that's a two-fold answer, especially given DTSC's limited resources. Part of it is, to the extent we have resources we'll do some kind of a secret shopper program. We'll do what we can to, you know, do Google searches, do research, all kinds of information that's on the Internet. And there's other folks behind me who have a much better idea than I on how to do that and what's out there.

And we're also hoping that manufacturers, NGOs, all kinds of stakeholders will come forward and tell us, hey, we're aware of this particular brand or this particular company that's making this product with bad stuff in it, we think you should take a look at it.

And we do have -- you know, I didn't mention it

but we do still have the petition process in there where anybody can petition us to consider adding a chemical or consider adding a product chemical combination to the list. When we do that granting a petition would mean we'd still use the same criteria that we would ordinarily.

So somebody could point that out, information out to us using the petition process or just, you know, sending us an email and telling us. So, you know, do we have a foolproof way? No. We're going to do the best we can.

CO-CHAIR GEISER: Okay, I have Kelly, Julia, Meg and Mike and I think that's going to be it. We have about seven minutes so try to -- oh, and Dele, okay. Okay, please keep your comments under 60 seconds, your question under 60 seconds.

PANEL MEMBER MORAN: I have a procedural question. I've got a bigger picture question about the regulations and then a very specific question about chemicals of concern. Is there going to be a time when we start talking about --

CO-CHAIR GEISER: There will be a time period for more open discussion, yes.

PANEL MEMBER MORAN: So I'll save the chemicals of concern question and just ask -- one of the science pieces of this is to understand how this regulation relates to the OEHHA draft regulations. And I was just wondering, Odette, if you could quickly enlighten us as to the approach that

you took in creating that relationship.

CHIEF DEPUTY DIRECTOR MADRIAGO: Certainly. And again, I'll try to be very quick. First of all, as I already pointed out, Melanie Marty from OEHHA has been with us every step of the way on this. We've also been, you know, reading and reviewing OEHHA's regulations so we're up to date on them. And as you will see throughout the regulations, when we talk about hazard traits we're referring right back to OEHHA's regulations. So when we say hazard traits or end points we're talking about everything that OEHHA lists.

And I guess the only other thing I would say is that in identifying chemicals and in -- actually in the definition even for the first list of chemicals of concern, a chemical that doesn't exhibit any hazard trait, and I understand that may be a very small list. But for any chemical that doesn't, they would not be captured as a chemicals of concern.

CO-CHAIR GEISER: Julia.

PANEL MEMBER QUINT: I just want to be reassured and also it's a point of clarification. When you talk about specific products like the teething ring with the BPA, the pure chemical consumer products are still on the table. I mean, like the toluene sold in the Home Depots of the world and things like that. Those are still considered, are still

being considered?

CHIEF DEPUTY DIRECTOR MADRIAGO: If they are on the shelf at Home Depot for sale or packaged for sale, yes.

PANEL MEMBER QUINT: Okay.

CO-CHAIR GEISER: Meg.

PANEL MEMBER SCHWARZMAN: One also just sort of reassurance. There's a couple of points where there's the ability to modify lists based on DTSC's awareness of presence of an alternative. And I assume that means bump it up in the prioritization process to sort of speed it through the process?

CHIEF DEPUTY DIRECTOR MADRIAGO: Yes, thank you.

PANEL MEMBER SCHWARZMAN: It doesn't say whether that's up or down.

CHIEF DEPUTY DIRECTOR MADRIAGO: Yes.

PANEL MEMBER SCHWARZMAN: Okay.

CHIEF DEPUTY DIRECTOR MADRIAGO: The answer is "yes" and good point.

PANEL MEMBER SCHWARZMAN: My other is a very short, specific question that's I think a legal one. And that is, there's the health trait association exemption that's a trade secret. That is, you can't claim information about the identity of a hazard trait in a trade secret claim. My question is, is that hazard trait linked to the identity of a chemical and the identity of the product? So

that is, you can't say, we're not saying whether -- the fact of this being a carcinogen is a trade secret. But can you say, this is a carcinogen but the name of the chemical is a secret? Is my question clear? Sorry.

MS. HECK: Yes, I think so. I don't know that we had contemplated that specific application of the regulations so much as drafting the general rule. So let me just start by saying the general rule comes right out of the statute. 27257 of the Health and Safety Code precludes -- it's an odd drafting -- a hazardous -- I believe that is intended to be hazard trait submission from being claimed as trade secret.

So all we did was elucidate slightly on the wording and say that it's information. Not literally just that information but information that is related to hazard trait cannot be claimed as a trade secret.

So let me give some more thought to your question because I don't want to answer off the cuff because I am not sure if it would extend to its end point as also being precluded.

PANEL MEMBER SCHWARZMAN: I guess I mean, if you say "the end point" can you redact the chemical name that the end point is about?

CHIEF DEPUTY DIRECTOR MADRIAGO: Can we say Chemical A exhibits carcinogenicity?

MS. HECK: Again, I need to think about that.

PANEL MEMBER SCHWARZMAN: Okay, thanks.

CO-CHAIR GEISER: Mike.

PANEL MEMBER WILSON: To protect those companies that step up and participate in the process and sort of in addition to the incentive and surveillance programs that you described are there other enforcement mechanisms contemplated in the regulations?

CHIEF DEPUTY DIRECTOR MADRIAGO: Yes, we have a whole section about duty to comply, which, you know, it starts out by saying a manufacturer has primary duty. If they don't do it then the importer does and then lastly the retailer. There are off-ramps for all three. You know, taking it out of the market in California for retailers, not selling it.

And there's a process where we provide notices of failure to respond or failure to comply. We post those notices. We have what's called a Failure to Comply list. Now that's not traditional enforcement but, you know, from the input we're getting that can be pretty effective.

But we do also have -- I should say and we also have our traditional hazardous waste enforcement authorities which are in our statute and embody, you know, things like enforcement orders and fines and penalties. They are not mentioned in the regulation because we don't typically

mention them in any of our regulation, it's just by effect of our statute by operation of law.

PANEL MEMBER WILSON: Okay, thank you.

CO-CHAIR GEISER: Our last question is Dele.

PANEL MEMBER OGUNSEITAN: Very briefly a couple. With respect to the product chemical combinations. I heard you say something about the legal defensibility of including that combination in the regulations but maybe I heard it wrong; I'd like some clarification.

CHIEF DEPUTY DIRECTOR MADRIAGO: Yes. Our attorneys advised us that we would have legal issues were we to specify, you know, chemical product combinations in the regulations so we did not go that route.

PANEL MEMBER OGUNSEITAN: But that will be the practice is what --

MS. HECK: I think what Odette was referring to is we were not doing the product categories as we had in the last go-around. Without getting into the specifics of advice that we have offered to the Director and staff, we've gone another direction that we think there's ample authority for us to do chemical product pairings later in the implementation of the regulations as opposed to up-front placing categories in the regulations.

PANEL MEMBER OGUNSEITAN: Thank you. And finally, chemicals that lack information will not be addressed in the

chemicals of concern list. But if an alternative were to be a chemical without information all the manufacturer has to say is, identify the gaps. Is that accurate?

CHIEF DEPUTY DIRECTOR MADRIAGO: That is correct. And that's going to be seriously taken into consideration when we look at regulatory responses. So, for example, if they choose an alternative that has very little information we would probably say, fill these specific data gaps by X date. Plus maybe you're going to have to provide additional consumer information as well as some other regulatory responses, just depending on the specific situation.

PANEL MEMBER OGUNSEITAN: Thank you.

CO-CHAIR GEISER: Okay, thank you very much, Odette, for laying out the new version for us and also for identifying the three questions, which we'll spend the rest of the time trying to address as best as we can.

For the record I'd like to welcome Rick Liroff who has now joined us and we will now move toward a break. Please remember our Bagley-Keene responsibilities not to discuss in private conversations, at least amongst a group of us, what we are here to discuss. So let's take a break until about say eight or nine minutes after the hour.

(Off the record at 10:57 a.m.)

(On the record at 11:11 a.m.)

CO-CHAIR GEISER: Okay, at this point we are open

to a public comment period. This is a chance for members of the public, either in the room here or outside who are on the web with us, to provide public comments. Radhika will be running this part of the public comments. Radhika, where are you?

MS. MAJHAIL: I'm right here.

CO-CHAIR GEISER: There you are. How many comments do we have?

MS. MAJHAIL: Right now we have four.

CO-CHAIR GEISER: We have four. I'm going to ask -- we have one from the web, okay. There's five that we have at the moment. Particularly for those of you who are not in the room and want to make comment, please remember that there is a kind of a short delay that takes place in the transmission. So if you are going to want to make a comment please let us know soon so that we don't miss you. Because somehow we cut you off before because we just didn't hear anything and it was really due to the transmission.

So Radhika, would you like to present our first public commentor.

MS. MAJHAIL: Dawn.

CO-CHAIR GEISER: How about three or four minutes, no more than that, thank you.

MS. KOEPKE: Excellent. Thank you. Dawn Koepke, I am with McHugh and Associates and representing the

California Manufacturers and Technology Association and I am also one of two co-chairs of the Green Chemistry Alliance along with John Ulrich. And we are pleased to be here today with you, as we attempt to be at every session you have, and appreciate the dialogue you have at each of those.

We as the Green Chemistry Alliance and industry as a whole are working on our point of view on the draft regulations. We have been feverishly working through that and obtaining feedback from all of our colleagues, which is mixed. And there's a lot that we are starting to find that we like about it, there's a lot that we think we still need to do some work on. And we commend the Department, staff, new Director Raphael for the work that they've done, being responsive to us and being willing to meet with us at every turn and hear what it is we have to say and our perspectives on things.

Relative to a couple of the things that we like about it with regard to the alternatives assessment process. We have advocated very strongly that there be flexibility in that process to account for the differences between products and even manufacturers and the processes that individually they undertake already. And we are starting to see signs of that flexibility in that AA process and we are very pleased with that.

Additionally relative to the certified assessors

versus third party verification certification. That is another issue that we are pleased that we're going in kind of more to the certified assessor route and allowing that expertise to reside in-house.

Relative to the concerns. We have a few concerns, and probably more than a few but nevertheless a couple that I'll just identify briefly. The chemicals of concern list, the list of lists. We have great concerns with that. We feel that the statute on not only the prioritization of chemicals but also for products calls for a process to be established and with that process clearer criteria for those decision-making points of what is brought into the process. And we're concerned that adopting a list of lists approach does not meet that requirement in the statute.

And even further than that, getting into the weeds specifically on the list of lists issue. We're concerned that the list will actually be far over 3,000 chemicals, particularly when you look through some of those lists and the fact that they not only take into account a particular chemical but reference the compounds of those chemicals as well that could easily lead us into far more than 3,000.

CO-CHAIR CARROLL: Dawn, please wrap up.

MS. KOEPKE: Thank you. We also have concerns with the prioritization process relative to, again, the process side of it and not as clear of a pathway and steps

to identify those priority products based on the list of lists, which is 3,000 or more.

And then we have concerns with de minimis threshold and other items as well.

Nevertheless we look very much forward to working with DTSC, continuing these discussions and listening to your discussion today. Thank you.

CO-CHAIR GEISER: Thank you, Dawn. Our next speaker is Gene Livingston from the American Cleaning Institute.

MR. LIVINGSTON: Thank you, Ken. I'm Gene Livingston with the law firm of Greenberg Traurig on behalf of the American Cleaning Institute.

First let me just embrace the comments that Dawn made. She spent so much time saying positive things that she really didn't get into some of the suggestions I'm sure she wanted to make so I'll not make that mistake.

(Laughter.)

One of the things that I think, if nothing else, Debbie will be famous for is having coined the phrase "meaningful, practical and legally defensible." And today we heard the Secretary of Cal/EPA embrace those standards himself.

In discussing the concept of meaningful he talked about choosing the most significant chemicals and I think

that's very critical. And I want to focus a little bit on the statutory provision that says that the regulations shall establish a process for identifying and prioritizing chemicals of concern in consumer products.

You'll notice that the regulation identifies chemicals of concern through the list of lists. There is no prioritization within those chemicals of concern.

Now I suppose you could say that the statute contemplates the prioritization could occur at the point of the product and not just at the point of the chemicals. That is a potential legal analysis.

But when you think about the unintended consequences of that, here is what you have. You've got a list of 22 lists with different kinds of outcomes included in that. And the assumption is that all of those are of equal concern, all of equal potency and so on. And even within the list, take IARC's list of carcinogens for example, you've got your A categories, you've got your B-1s and B-2s, probables versus possible. So there is a potential prioritization process to get at the most significant chemicals, which is not present in this regulation.

We also understand that one of the rationales for having a big list and not prioritizing it down is to prevent the regrettable substitutions. And the phrase was used that

that often occurs. The only experience that I am familiar with where substitutions have been made is in the context of Prop. 65. It's an area where I have worked since the passage of that initiative. And it's been rare that there have been regrettable substitutions. There have been some manufacturers, I think, who have perhaps taken advantage of that. But when you look at the manufacturing process, to reformulate products --

CO-CHAIR CARROLL: Gene, I need you to wrap up.

MR. LIVINGSTON: Okay, thank you, Bill. When you look at that process the goal is to look at all of the toxics and to come up with an ingredient that works best in that product. And it depends on the use of that product, the route of potential exposure, all of those things go into it. So that discouraging substitutions without having to go through the AA process is not a good thing, it's an unintended consequence. Thank you.

CO-CHAIR CARROLL: Thank you, Gene.

CO-CHAIR GEISER: Thank you, Gene. Our next speaker is Davis Baltz from the CHANGE Coalition.

MR. BALTZ: Thank you very much. I'm Davis Baltz with the NGO Commonweal in Bolinas, California and the CHANGE Coalition, Californians for a Healthy and Green Economy.

Given the time constraints I am going to limit my

remarks here to the important issue of de minimis. But let me say in general we believe this iteration of the regs to implement 1879 is vastly improved over the failed effort of late 2010 and we look forward to submitting detailed comments as well as participating in the December 5th public hearing.

CHANGE has always maintained that a default de minimis threshold applied across the board. It's not scientifically justified because different chemicals can have health impacts that greatly vary in concentration. We therefore are gratified to see that DTSC has laid out a process for setting de minimis levels in these regs that break new group.

First, DTSC has lowered the threshold for chemicals exhibiting one of nine specified hazard traits to .01 percent by weight, as Odette has laid out. This approach recognizes that a universal de minimis exemption of just .1 percent for all chemicals fails to account for the current scientific understanding of low dose effects.

Second, DTSC has specified that the de minimis level be set for the cumulative concentration for all chemicals of concern that exhibit the same hazard trait for environmental and toxicological end points in a priority products listing. Capturing the cumulative nature of human exposure to potentially harmful chemicals in chemical

regulations is long overdue and we commend DTSC for taking this forward thinking step.

Third, DTSC retains the authority to set a lower or higher de minimis level if scientific evidence warrants. This provision demonstrates that DTSC is incorporating current and emerging science that shows with increasing clarity that some chemicals can cause effects at very low doses far below .1 percent or .01 percent. The ability for DTSC to set a chemical-specific de minimis level is an essential piece of DTSC's approach in our view.

So in conclusion, we support the way DTSC is proposing to grant de minimis exemptions but would make one important recommendation, which is there should be no exemption for carcinogens, mutagens, reproductive toxicants, endocrine disruptors or persistent bioaccumulative toxins. We already know these classes of chemicals can have adverse health effects for people and therefore all of them should enter the alternatives assessment process. Thanks for the chance to comment.

CO-CHAIR CARROLL: Thank you.

CO-CHAIR GEISER: Thank you, Davis. Our next speaker, fourth speaker, will be Douglas Fratz from the Consumer Specialty Products Association.

CO-CHAIR CARROLL: I'd like to remind everyone on the web that it's time to get your comments in now, please,

if you intend to make them, thank you.

MR. FRATZ: Good morning. Yes, I am Doug Fratz at the CSPA. We represent formulated products and are a member of the Green Chemistry Coalition -- Alliance.

I want to make a couple of points regarding the goal being practical and meaningful, which we of course very much support in this regulation.

The broadness of the COC list being proposed was already brought up, the over 3,000 chemicals. These chemicals will have very -- all of these chemicals, of course, have hazard traits. All chemicals have hazard traits at certain levels of exposure and environmental concentrations. They all also have exposures and concentrations where effects don't occur.

So it can be argued that you should have a broad group. But you need to take that into account, for instance, because many of these are used intentionally in consumer products but some are almost ubiquitous in the environment and all consumer products will have a chemical of concern at some concentration, often many of them. So when you say a product with a chemical of concern you're talking about all consumer products.

Second, the broadness of the definition of consumer products. It's reasonable to try to make this regulation apply to every type of product that a consumer

might get but this is -- it must be kept in mind how many millions of consumer products there are, individual consumer products. And even in the narrow categories that Odette mentioned there could be tens or hundreds of companies with ten or hundreds or thousands of products. So if you're asking, you know, identification, all these companies to identify that they don't have a chemical of concern, that could be many thousands of analyses that are required to assure that.

The third, looking at what an LCA is. To be meaningful you've got to use tools for what they're made for. And the LCA was designed for looking at all of the impacts of an alternative throughout its life cycle and seeing where the significant impacts, where the significant benefits, to see how they can be optimized and improve the product to process.

It wasn't designed particularly to decide and compare between two products or processes. And what they mostly find if you use them is there are pluses and minuses to either. You have to -- and if you can design this process to make use of that so that you're looking to optimize the pluses and reduce the negatives, you'll --

CO-CHAIR CARROLL: I need you to wrap up, please.

MR. FRATZ: -- a better stead. Also the timing is key. It's important to realize that because of the quick

timing of this you are looking at existing products. There is no -- it takes three to ten years to develop a new product so you're not going to have the opportunity to develop a totally new alternative.

CO-CHAIR CARROLL: Thank you.

CO-CHAIR GEISER: Thank you. And we do have one comment.

MS. BARWICK: One comment from the webcast. The comment is from Maia Jack, Ph.D., who is the Senior Manager of Science Policy and Chemical Safety for the Grocery Manufacturers Association. She has a list of questions that I believe are directed to the GRSP for their consideration in their discussions and I'll just read it to you:

"How are multiple COCs assessed in a priority product once a particular COC product combination has been identified and prioritized? Would an independent alternatives assessment be required for each COC in a given priority product or would the focus of the alternatives analysis be only on the identified COC in the product? In other words, how would a manufacturer do an alternatives assessment on a particular chemical product combination when multiple COCs are present in the product according to the chemicals of concern list? Thank you."

CO-CHAIR GEISER: Thank you. Are there any additional comments from either those of in the room or on

the Internet?

Hearing no more comments I believe we will close the public comment period. Thank you very much all of you for your comments, very helpful.

At this point we now move into the body of our discussion, of the Science Panel's discussion, and I'm going to turn this over to my co-director. We'll spend the rest of the morning on kind of a general discussion of what you've heard, what you've seen in the new text. And Bill, if you could carry us here.

CO-CHAIR CARROLL: Thank you, Chair. It's wonderful to be back at the microphone. We have a number of opportunities for discussion over the course of approximately the next 24 hours. This first opportunity, you will notice from the agenda -- well perhaps you don't notice from the agenda. I notice from the agenda it says "Frame the GRSP discussion." This is, of course, always dangerous to attempt to get the GRSP to frame its discussion. It's almost as dangerous a question as saying, clarifying questions only.

(Laughter.)

But what I'd like to do is direct the discussion here to the general kinds of reaction that you might have that do not specifically involve the questions that have been asked. And the reason for this is because we picked

three more or less rifle-shot areas that we wanted to go into depth and give you adequate time to discuss. At the same time we recognize that this is your first opportunity to discuss the regulations in their totality and wanted to make sure that you had an opportunity to take kind of a general view.

In addition, for those of you who will not be present tomorrow, this is your opportunity to react to the kinds of things that, well for example, tomorrow where we're discussing Question 3. To react to Question 3 in addition making your general comments.

And so with that I would ask if there are, if anyone has any general sorts of comments, over-arching considerations that you'd like to get into? The way we do this, by the way, is you take your tent card and you turn it up on the end. On the other hand, if you don't have anything to say -- I was about, I was about to dismiss us for lunch, Tim. I don't know.

(Laughter.)

All right, there's one in every crowd. All right, counselor, you're up. Then I'll just make a list from -- you were reticent there for a moment. That's fine, I'll make a list. Tim, it's all yours.

PANEL MEMBER MALLOY: Thank you. I actually had a clarifying question, which was, were you reserving this time

for folks who won't be here later or is this --

CO-CHAIR CARROLL: No, not exclusively.

PANEL MEMBER MALLOY: Okay.

CO-CHAIR CARROLL: For general comments. But specifically for those who won't be here later, this is your opportunity to react to Question 3 and general comments.

PANEL MEMBER MALLOY: Okay. I just wanted to make a couple of general comments. One is, I kind of share the optimism that this is, this I think is a really nice and in many ways elegant piece of work and shows a lot of creativity in how to deal with a very, very comprehensive program under extremely difficult conditions of a lack of resources. And I think it does show a lot of responsiveness to a lot of the different comments you've received, not only from us but from other folks. I am very positive about it.

I did have, I thought there were a couple of things that struck me that aren't -- I mean, I could fit them in within the three questions and maybe I probably will over the course of the next couple of days but I just wanted to highlight a couple of things that were of some concern to me and I'm not sure exactly how it plays out.

The major one was, I certainly understand the point that on the alternatives assessment the idea is to create a mandate to have manufacturers ask the question. Essentially do the analysis and look to see if there's

viable alternatives but not to mandate the answer. So kind of this, you know, you manage what you measure. So if you make people think about these questions and consider them, that's going to be of basic value, even without government trying to affect the outcome, which I think is a legitimate way to think about things, although I think not complete.

And I was worried that, that the regs themselves seemed to have no standards for decision-making in them. They have a -- I think they have a very useful decision structure and there is some -- I think built into them are some attempts at creating weighting, inherent weighting. For example, in the prioritization process the way you've laid out the decision structure.

But on the alternatives analysis process it seemed to me that there were really no standards for making the evaluation itself. The criteria are laid out but there's -- so my concern is that there's not going to be a lot of consistency across cases.

And I am also concerned that saying that the way that you would deal with that is through the regulatory response raises some concerns for me because there's also no standards for the regulatory response. Under what circumstances particular things would happen.

So that along with my concern about an inability to get information generally are the major problems I have.

And the information part of it goes to -- it's not clear to me once you have that list of the 3,000 or so, call it the 3,000, that where will the information come to allow you to make those product chemical comparison linkages?

Clearly there's some available information out there but one of the problems a lot of folks who deal with the chemical ingredients area talk about is that there's really not enough information to pair chemicals, what chemicals are being used in what products. And to me that seems like a major obstacle to doing the chemical product pairings. And I didn't see anything in the regs that seemed to address that particular issue. Thank you.

CO-CHAIR CARROLL: Thank you, Tim. And I am going to just go ahead and feed my obsessive-compulsive disorder. I'm going to start here with Kelly and just work around.

PANEL MEMBER MORAN: (Microphone not on.)

CO-CHAIR CARROLL: Well you put your card up.

PANEL MEMBER MORAN: (Microphone not on.)

CO-CHAIR CARROLL: All right, all right. So we've had a revolt already. Bob, would you care to bail Kelly out?

PANEL MEMBER PEOPLES: My pleasure. And I worked hard on this following line but I wanted to say, I am not a regular reader of regulations. I thought I would trip up on that one. But I do have two, two questions for I think

clarification, at least in my mind here.

And that is, on page two of the summary document I'm looking under B. The first paragraph refers to, you know, apply to all consumer products manufactured in California. And then in the subparagraph (2) bullet it talks about the exemptions and it specifically talks about manufactured in California solely for out-of-state, which I assume means it's not going to be put on the market in California.

But I'm wondering if by saying you can manufacture it in the state of California if its only for shipment out of the state of California, if you still have issues of human health and environmental impact concerns that are not going to be addressed by the spirit of the law in these regulations? That's my first one.

CHIEF DEPUTY DIRECTOR MADRIAGO: That's a good question. We probably need to think about it, both from a legal standpoint and a meaningful standpoint.

PANEL MEMBER PEOPLES: Okay, fair enough.

CHIEF DEPUTY DIRECTOR MADRIAGO: I'm just going to note it if that's okay with you?

PANEL MEMBER PEOPLES: Okay, all right. The second one is on page 12 of the summary. It's under the second, the number two bullet. And it's the fourth bullet item down the page which talks about "A demonstration that

the manufacture, use and disposal of the selected alternative ..." And as I read this in the context of the alternative selection decision process it occurred to me, is this, in fact, resulting in a regrettable substitution by the way the language is crafted?

And you may need to think about that one a little bit also. Because the way the word is written it says "Of the selected alternative ... will have no greater significant adverse public health or environmental impacts than the impacts associated with the Priority Product."

CHIEF DEPUTY DIRECTOR MADRIAGO: Um-hmm.

PANEL MEMBER PEOPLES: So to me that's sort of equivalent to a regrettable substitution if there is no difference in the characteristics.

CHIEF DEPUTY DIRECTOR MADRIAGO: So when you think about that, what we were trying to get at with that paragraph is that, I mean, that's like the floor.

PANEL MEMBER PEOPLES: Okay.

CHIEF DEPUTY DIRECTOR MADRIAGO: That, you know, we don't want them to go below.

PANEL MEMBER PEOPLES: Right.

CHIEF DEPUTY DIRECTOR MADRIAGO: And so hopefully they're going to go above. It's probably fairly safe to say that if they don't go above they're probably guaranteed a regulatory response of some kind.

PANEL MEMBER PEOPLES: Okay.

CHIEF DEPUTY DIRECTOR MADRIAGO: But we'll go back and look at it.

PANEL MEMBER PEOPLES: Okay, all right. I may need to ponder that one a little bit more myself as well, thank you.

CO-CHAIR CARROLL: Thank you, Bob. Meg.

PANEL MEMBER SCHWARZMAN: Thanks. Just keeping with the sort of general here. Obviously we have time to get into a couple more technical things.

But first of all I want to echo what is starting to be a theme that -- and just applaud DTSC for real substantial changes that add internal consistency, clarity and a general picture of -- it's like I can follow this and see what would have to happen. So a lot more detail about mechanisms and how companies and anyone else who falls within the purview of the regulation would respond and make this happen.

So as a reader of the regulation I deeply appreciate it, and as a reader of multiple versions of it. We are all becoming regular readers of regulations. So I think there's huge strides that have been made in terms of clarity, readability.

Also something that we have asked for in the past I feel like is in here, which is communication of an intent.

And we felt in the past an absence of guiding principles, in a sense. And I feel like although there isn't a bullet point list of guiding principles at the beginning that that's communicated in intent throughout the regulation. And that also, I think, is very, very useful.

Also I want to acknowledge in response to one of the public speakers that of course if you take the 3,000 chemicals times the however many products times the however many producers and retailers and importers you can come up with vast, vast numbers and a universe that these regulations could potentially affect.

And I think that's on purpose because one of the main stated goals of this all along has been to avoid regrettable substitutions. And you can only do that by allowing consideration of a very broad universe of chemicals and products and bring all the producers under the tent.

And yet I feel like DTSC has within that very large universe laid out very precise steps for how it's going to be done in a step-wise way. And, you know, the idea that DTSC will identify specific product chemical combinations and the actions will be taken on the nose in step-wise process I think completely answers the public comment concern about the scope and reach of these and the implication that that will create chaos and be impossible for producers to carry out.

And furthermore on that point I think, isn't it a reasonable thing to request that the producers and sellers of chemically intensive products understand what's in their products and have governance over that. So the fact that we have to play a huge amount of catchup doesn't mean we shouldn't be doing catchup. It means there has been a long time where it's been vastly under-governed. So I just wanted to kind of respond to those ideas that were coming up in public comment because if from the outset we limit the scope to what seems possible today we have undersold ourselves completely.

And finally, let's see. There's a bunch of things that I want to applaud but those are some broad points. In terms of a couple of things that I think DTSC should look out for. One is I appreciate the increased attempts to roll worker exposures into this. And I think there will be a couple other places that I want to flag that I think we need to, where workers are being left out. And one of them actually is this point that Bob brought up about, if we're manufacturing products and chemicals in California but shipping them out we've ignored a whole bunch of potential worker exposures there.

In general two places that I see DTSC being able to -- boxing itself in if we're not careful. This is my final point. There's two ways that DTSC could avoid boxing

itself in. One is, in general during the prioritization process, not to pin yourself, hold yourself to the standard of identifying the most highest priority, most threatening chemicals and chemical product combinations.

It's a standard that you'll never achieve, that will be contested infinitely and that will slow progress. And so I think that shouldn't be the goal. And I've seen places in the regulation where you have helped with that by including things like, availability of information, availability of alternatives. Those sorts of things that can influence how you prioritize and list chemicals and products. All of those have down sides. But I think I'm seeing ways that you're trying to avoid that problem and there may need to be a few more of those. We can get caught in the "we have to identify the worst actors" and I think that's a mistake.

Similarly in a same way you could avoid boxing yourself in with alternatives assessments by not limiting them to alternative chemicals. And there's a couple of examples of this and I think we can get into more -- I don't want to take more time now but just as a frame.

CO-CHAIR CARROLL: Thank you, Meg. Michael.

PANEL MEMBER KIRSCHNER: Okay, thanks, Chair. I just want to echo everyone else's commendation of DTSC for this draft; it was much easier to get through and

understand. As well as all the summary docs, awesome. Even the pretty drawings, very helpful. Although I really do like showing that flow chart to people and saying, this is what it's like. Neener-neener. So this is going to make that job a little tougher.

(Laughter.)

Actually I have a couple of real detailed issues because I am not going to be here tomorrow. Because the eyes of the world are on you all at DTSC, everybody is watching this. I'm going to Europe to tell them what's going on here so watch out.

Actually on page 33 of the actual regulation, the priority product notification, paragraph (a). If a manufacturer -- that's 69503.6(a), page 33. If a manufacturer produces a priority product but it does not contain a chemical of concern do they have to notify the Department? It says here they don't have to notify the Department if they have submitted a de minimis notification. And I guess the de minimis notification is accepted. But if it's -- maybe I'm misreading this. But if they don't have one, if they're making that teething ring without BPA, they shouldn't have to. I think that needs to be spelled out if it's not already in here. So just a minor point of clarification.

The other point I wanted to make, and I already

sent this in as a suggestion on page 31. The de minimis exemption for -- because I don't see it listed here when we're going to talk about de minimis. For an assembled product I think we need to add another definition in here. The cumulative concentration in each component that is a basis for the priority product listing is what's listed by the cumulative concentration. But that's not clear.

In an assembled product you're typically going to have one material that's the source of the exposure for a given chemical of concern. And it's that material that you want to focus on in the assembled product. And it may be per COC. And the only definition I'm aware of for how to deal with that is out the European Union's ROHS restriction on the use of certain hazardous substances and electronic product directive where we look at the concentration of a substance in a homogeneous material.

So to use Kelly's brake pad example real quick. The copper in the brake pad is what we're after and that pad is a homogeneous material. We are not interested in the copper that's perhaps in the backing plate that the pad is attached to, if there is any. Let's say there is. We don't care about that because that's not the source of the pollution. It's the pad itself and the pad material.

That's the detail point I wanted to make. But otherwise we'll talk about other things later, thank you.

CO-CHAIR CARROLL: Thank you, Michael. I have Dele then Art and Jae.

PANEL MEMBER OGUNSEITAN: You skipped Joe.

CO-CHAIR CARROLL: I know. He put his up later.

I wasn't going to disenfranchise you, Joe, at least not totally.

(Laughter.)

PANEL MEMBER OGUNSEITAN: Okay, thank you. I echo the thoughts that this is a major step forward in constructing this document. I focused on the alternatives assessment, in part because I agree that this is really where the creativity and the innovation of California's leadership is.

One of the concerns that we have had all along is that this can potentially overwhelm resources, given the scope of chemicals and products. We just heard a comment this morning that it's potentially thousands and thousands if not millions of products would be affected.

So I was looking at the quality assurance aspect of this and the creation of a certificate program for assessors. I am not convinced there is going to be a lot of benefit out of the public posting of non-redacted forms but I think, as we heard this morning, we'll only know once that process is started.

But to use DTSC's resources better or more

effectively and efficiently I was thinking of another way to prioritize the level of rigor required for the alternatives assessments and in so doing make those responsible for conducting the assessments, anywhere from the manufacturer to the satisfied independent workers, to DTSC's audits.

So you could have an easy elimination of the chemical of concern, for example, or reduction below de minimis level; replacement with another COC, which increases the rigor; replacement with a non-chemical of concern; or worse, replacing with something we don't know anything about. So I think some thought needs to go into how to look at these categories and expect different levels of rigor for the alternatives assessments and distribute the tasks accordingly. Thank you.

CO-CHAIR CARROLL: Thank you, Dele. Art.

PANEL MEMBER FONG: Thank you, Chair. One of the recurring themes and concerns that we have heard throughout this process is in terms of, you know, chemicals in products regulations. It's how overburdening regulatory frameworks can block product innovation in the state of California.

You know, I've given that quite a bit of thought because I am in industry. And actually how I look at this is not so much how much regulation but how smart the regulation is. So if you look at countries like Germany and Norway, they're heavily regulated but yet they're highly

innovative.

So when I went through this set of informal set of, you know, set of informal regulations, my take on this is, this is really smart. Again, I just really like this. So again, smart regulation is the way to go. However, that's not -- like George, that's not to say I don't see areas for improvement. Thank you.

CO-CHAIR CARROLL: Thanks, Art. I have Jae and then Bruce, Mike Wilson and Joe and then Kelly. Jae.

PANEL MEMBER CHOI: In terms of the summary, I just want to indicate a couple of things that the last three years repeated questions arise in terms of DTSC's role in spite of the, you know, the shortage of resources in the Department. But I think, as Arthur said, that very smartly increased the DTSC role. You know, example that Odette summarized this morning. Very much the DTSC role has been clarified and specified.

You know, one of the things that I was delighted to see, you are actually going to help manufacturers in terms of complete forms. It may be a very simple form, I don't know, but I think that's one example that I to proactively involved from the part of your team.

And the other one that until last meeting, I think, we have heavily discussed about the third party certification versus the certified assessor. I think it is

very wise to eliminate, you know, the third party certification and then try to have the certified assessor. So overall I am very happy to see this becomes a more practical, more meaningful approach.

Right now I have one clarification or questions maybe rise later on. I don't know much about regulations. But in terms of potential exposure to health and environmental exposure on chemicals of concern. You know, market presence information for the product, I'm not sure what that means in terms of what that means in terms of how to get it and how to regulate. Thank you.

CO-CHAIR CARROLL: Thank you, Jae. Bruce.

PANEL MEMBER CORDS: A very valuable piece of information is the key milestones page. Because everybody in the outside world wants to know after the puck drops what happens next, right? In looking at that and then -- and also I commend you on going with the certified assessor program.

But when I look at page 59 of the actual regulation it says "on or after January 2015." And that seems to me that's going to be too late. Depending upon, I guess depending upon when the effective date of the regulation is because you've got assessors who need to be involved like a year after. So I was just concerned on that. Because even prior to that you're going to have to

have certification bodies, authoritative bodies that are going to actually certify the assessor. So it seems to me 2015 is late.

CHIEF DEPUTY DIRECTOR MADRIAGO: Let me real briefly say something. I'm glad you said that. That's something I meant to say during my presentation and forgot. We put that date in there because we were concerned that there wouldn't be the capacity to have enough lead assessors up and running and certified to do the early round of the AAs. So we were recognizing that the first round would not have lead assessors. Something you may want to discuss when we talk about this process.

PANEL MEMBER CORDS: Okay.

CO-CHAIR CARROLL: Very good. Thank you, Bruce. Mike Wilson. Jae, please put your card down, and Bruce.

PANEL MEMBER WILSON: Thank you, Chair. And again I also appreciate the clarity and also the intentional process that DTSC went through in really engaging the Panel and seeing a lot of those discussions reflected in this outcome. Just really appreciate that.

So I just have a couple of things. One is pertaining to the chemicals of concern list and then another has to do with the question of occupational exposure. But pertaining to the list. I think part of the reason that, that there's a need for a fairly sizable list is that we're

way behind on this issue in terms of regulation and public policy. The science has continued to roll out and that's been reflected in the deliberations and the outcomes of thee various authoritative, scientific bodies around the world and so we're playing catchup.

And I think it's, you know, we're making a smart decision. Getting to Art's point. It makes sense to rely on those decisions that result from deliberative, authoritative bodies and dispense with the dueling risk assessment approach and use that as our foundation.

Also, you know, Meg's point about you've clarified why it is that we're doing this. We want to send a message to the market, we want to give a foundation from which companies can build, and we want to introduce some predictability.

Odette mentioned how some companies are beginning to do this already. Those are the large companies that are able to hire consulting firms an so forth. It's difficult to gather this information. We're finding this in our work on campus. It's taken us a year and a half to -- you know, working with a chemist and an information scientist to pull this information out of PDF documents and so forth and put it into a usable form.

Large companies like Walmart and so forth have had to hire consulting firms to do this work for them. So I

think by doing this you're providing an extraordinarily important service to California business, particularly those in the small and medium size enterprises that are just not going to have the resources to do it.

We heard at a Cradle to Cradle conference a week and a half ago mostly from investors here in California that the highest priority was what they described as radical transparency in the market. If we're able to -- whatever we can do in these regulations to put a predictable base of information out from which people can move the market will respond and will do so rapidly, you know, notwithstanding the comments from Doug Fratz. In some cases they described market responses within months to this kind of input.

With regard to just specific suggestions. I want to reiterate being careful to include workers intentionally throughout his regulation. And again this gets to Art's point about smart regulation. We can do a lot through this process in protecting workers through upstream strategies. And our primary regulatory and policy structure in California, with the exception actually of the Occupational Health Branch within the Department of Public Health.

But Cal-OSHA's work or the Division of Occupational Safety and Health work is primarily end of pipe work. And they're really grossly understaffed and -funded relative to the 18 million workers in California. Anything

that we can do to integrate our efforts within state government to protect people on the job by reducing the number and the nature of toxic materials that are placed into their hands is smart government. It's smart public policy and regulatory policy.

A specific example of that around end-labeled consumer products. You know, since our work with HESIS and the Occupational Health Branch around products used in the automotive repair industry we found that 90 percent of the end-labeled consumer products in that industry were used -- on the market were used by workers; 10 percent were sold to the consumer market. And those were products that were available in, for example, Kragens. They were end-labeled consumer products, they weren't Ford company-specific products or so forth. That means that in the definition of consumers we be careful. You're careful to make sure we're not excluding workers in that process.

And then the second is on the lists themselves. I have four quick additions if that would be all right with the Chair.

CO-CHAIR CARROLL: I think you may want to save that for the discussion about the chemicals themselves.

PANEL MEMBER WILSON: Okay, that would be fine. Okay, thank you, Chair.

CO-CHAIR CARROLL: Thank you, Michael. Let's see,

Joe, I have you next and then I have Kelly and Richard.

PANEL MEMBER GUTH: Thank you, Chair. I just want to -- I share the feeling that this draft regulation is a really good document to be working from. There's a lot of internal consistencies and a lot of thought has been put into it. I think there are a lot of things about it that are smart and I also just extend my congratulations to the staff and team for doing this.

I just want to mention a couple of things that I don't think fit into the questions that have been asked. One is I share the concerns about workers. There are a number of places in the regulations that I think leave out analysis that would pick up their concerns. And maybe we can go through that in a little more detail.

But it's just the limitations in the life cycle will be considered. It just starts at the product and not the creation of the chemicals in the first place. Only products that are made for sale and use in California are considered. There are a lot of workers in California making products that are going to go outside the state. That seems to not be considered. Bulk chemicals being excluded as potential priority products. That's not required by the statute. I don't know why you'd do that in the regulation but that also, you know, becomes a workers issue. And I think there are one or two other places like that where

they're sort of -- almost structurally makes it difficult to get to workers' exposure issues.

The second thing I'd raise is in respect to nano materials. The definition of chemicals is quite narrow in this regulation. It describes them as, you know, discrete molecular entities. So we know nano materials are these sort of large superstructures of chemicals that aren't -- probably nano materials don't fit within that definition of chemicals. And so I guess the issue is if there's a nano material that's comprised of chemicals that are not themselves chemicals of concern it might be completely left out of this regulation.

And I'm not sure if that's the intent. I don't think it's required by AB 1879, any of the definitions there. I think people were very confident that nano materials could be included. These regulations seem not to though allow for that possibility.

And then the last thing that I'd mention is -- maybe it's more of a question. I think the idea of 3,000 chemicals for the reasons that Odette outlined to try to cut off some of the regrettable substitution problem, that is a smart idea. There are lots of implications of that. Mike mentioned some, there are others.

But of course it doesn't cut off the whole regrettable substitution problem. There's probably an

endless number of possible toxic chemicals. And it's -- obviously the easiest way out of these regulations is as soon as -- let's just move away from those 3,000 COCs as soon as you can.

So a lot of people have advocated a minimum data set, right, for chemicals in commerce as a separate policy mechanism. So my question to this team after you guys have looked at this, you know, is -- and that's not included in these regulations, minimum data set. So my question is whether you are not doing that as a policy reason or you plan to get to that later or whether you've decided that can't be done under this law?

MS. HECK: That's a fair question, Joe. We have erred on the side of caution. I don't think we've ruled that we had a complete lack of authority to compel information during the alternatives assessment stage. We thought it was more prudent and appropriate and certainly tracked more closely to the literal language of the statute to move that task to the regulatory response stage of implementation.

So we have asked that manufacturers or responsible entities identify data gaps and we have reserved to ourselves the seek more information to fill those data gaps during the regulatory response stage, since that's the way the statute really speaks to compelling the submission of

information.

PANEL MEMBER GUTH: Chair, could I clarify my question?

CO-CHAIR CARROLL: Certainly.

PANEL MEMBER GUTH: I am asking more about closing data gaps for unknown chemicals; so chemicals that are untested out there. They're not on lists of lists and there has been no data required about them as a condition of putting them in the market. So the idea would be to crete a minimum data set that's required of all chemicals in commerce that then -- that would be part of the process for identifying COCs in addition to the 3,000. That's what I'm trying to get at is a minimum data set issue.

There has been legal argument back and forth whether that's possible because you have to do that to identify all the COCs because there are chemicals out there that are of concern even though we don't really know it. So that's what I'm trying to get at.

And the reason it's important is, there's a concern with a comprehensive policy that would include that element. We don't know whether this is something that you're planning to do or might do or think is possible under 1879 or whether that's a legislative -- an issue for the Legislature. And so I am trying to get your sense to the extent you can tell us after taking a fresh look at all this

the last six months.

CHIEF DEPUTY DIRECTOR MADRIAGO: So one of the changes that I didn't highlight but that if you read closely you'll notice in the regulations is that -- and here I'm going -- it's like, it's in the first article and it's the section on chemical and product information.

And the prior version of the regulations had provisions in there under which the Department would first seek to obtain information that was publicly available. And then for information it thought it needed to do prioritization it would require manufacturers to submit the information.

Our attorneys did not feel that that was a legally advisable approach to take, without going into any further detail unless Colleen wishes to do so. And so we have instead taken the approach that we will request that information. If people who receive a request don't provide the information we will have a list that says, you know, failure to respond. This is a similar approach that we used for 289, because 289 really only had legal mandates on in-state manufacturers. But we use this approach with out-of-state manufacturers and I think Jeff tell me it works fairly well.

So I think bottom line, Joe, is that, you know, I don't know if you're talking no data/no market. But I think

to mandate a minimum data set of any kind up front, do think that that is outside the scope of AB 1879.

CO-CHAIR CARROLL: Thank you, both. Kelly, it's yours.

PANEL MEMBER MORAN: Thank you And I'm cognizant of the fact that I'm one of the last few people between us and lunch so I will try to keep this brief. I have a few minor points and then one major point.

But before I start I want to echo the congratulations to the Department and thanks for really stepping back and thinking this through and creating a framework that was based on science. And I see science under meaningful, practical and legally defensible. I see how you brought the input of this group in here and you created a scientifically robust process here.

As I look at this I have very few comments on framework and I'm tending to get down into the technical details. I am still -- so part of why I was asking Bill for a little more time is I was expecting this conversation tomorrow. But I am still circling around about what "environmental impacts" means and going through all the definitions. And there's some places like that where I really want to still think about that.

But I find what I'm doing is looking at, well here technically this might mean this and perhaps -- my

experience is this so maybe if this were reworded in a different way. So those are things I'll be thinking about in coming weeks and providing some suggestions to the Department as to how to address those. But those are much more technically based.

A couple of things just in response to things we've heard here. Somebody said, gee, there might be too many chemicals of concern to manage. And I've seen the really fabulous example of the GADSL, it's the Automotive Declarative Substances System (sic), something like that. But it's basically a system whereby manufacturers are requiring suppliers to provide these kinds of data.

And as was mentioned before, getting all that stuff together was actually a big thing. Manufacturers are getting their suppliers to tell them and then they're going ahead of mandates and saying, you know, asking for, can you start innovating in these particular areas.

Like Art I think that having the longer list is a key piece of the strive for innovation that the state is seeking for and that I see in the framework here.

Another thing I just want to briefly mention is I have a lot of experience with the pesticides regulatory framework, which is one of the few other ones in the world that seeks to regulate a class of products to prevent environmental harm. And from that I've learned two things.

One is that in pesticides the history is replete with the examples of regrettable substitutes.

And I've spent much of my career working on regrettable substitutes that were made because of the regulation of one chemical without thinking about the big picture of the others and without enough signals about what's going on with the others. I could go on at great length on this but I won't in the interest of lunch time coming up. If anyone thinks there is any reason not to do that I would be happy to belabor that.

The other thing I've learned from that is that we need to be careful about our definitions of the use of the product and the life cycle of the product. One of the regrettable things that have been done in the pesticide regulations is not to include reasonably foreseeable use and even misuse of a product and mismanagement of it. People often don't read the instructions and don't do what they're supposed to be doing so we have exposures, human and environmental exposures that occur. And sometimes it's reasonably foreseeable.

For example, not in pesticides but just in life, lead wheel weights fall off of vehicles. And those actually were found out to be a non-negligible source of water pollution. So that's something if you were just walking through this and doing it in the normal way you wouldn't

capture.

Finally to my larger point. Going back to the themes here. We're looking for meaningful, practical and legally defensible. And I am struggling with the meaningful part here because of the narrow scope of the -- the magnifying glass here. So I'm thinking about that a lot. And I'm recognizing that the Department doesn't have infinite financial resources and thinking about what that means.

And what I'm worried about is that the goal of 1879 and 509 was trying to say, let's have management of pollution from products be something that scientists do at government agencies rather than something that legislators do, most of whom are not scientists and are working in an environment where they don't think things through like we all and the agency staff here do.

And my fear is that if the program is too small that we're just going to -- it doesn't have the capacity to deal wit all these costly problems we have out there. We're going to be back in the Legislature doing all this stuff. There's going to be this really intense problem there. And the answer to that is probably outside of this room.

But just to make sure I've really driven this point home, if you think about the last few years what's happened in the Legislature, there have continued to be

products -- pollutant and product legislation. And going back to the lead wheel weights, copper in brake pads, we have had a variety of mercury-containing products. I'll note that all of those pieces of legislation were very important to not just to the environmental community but also to government agencies and had substantial cots involved and cost savings involved for the taxpayers of California.

We have a lot of pressure and some regulations going around, the problem with disposal of wastes at end of life because they're hazardous. Things that we haven't yet tackled, pHs in pavement sealants is becoming a big national issue. We've got PCBs in paint that are being used, certain colors of paint contain PCBs, some new kinds of PCBs. Another one that's been around forever, halogenated solvents in toilet additives that then get dumped into septic systems at campgrounds and were causing groundwater pollution from those. Some of these are very small, focused problems.

But when I look at the structure here I'm a little worried that the demand just for that short little list of things that I'm aware of that are from a water pollution focus, isn't big enough. And so I think it sends us back into the Legislature.

So as I'm reading this I'm still thinking about, is there some way to frame this that could help with that

problem or is that answer really outside this room and in a discussion of what are we going to find as a state to do that. Would we rather continue with legislators, do that, or would we like to have scientists make those decisions. Thank you.

CO-CHAIR CARROLL: Thank you, Kelly. I have Richard, Ken and Julie. And I think that will probably about exhaust us so let's go ahead and do that. Richard.

PANEL MEMBER LIROFF: I'll be very brief. I agree with all the positive comments about the progress to date in the regulations, agree with the comments about thinking about the workers. A philosophical riff, taking of where Kelly left off and picking up some of what Art said.

Which is, actually we have to keep in mind what the objective is here, you know. We're talking about green chemistry. The pieces of green chemistry that can be accomplished through regulation through the government, at least at the state level, within existing resources, is very, very limited. And I full understand that you need to get the regulations to the point where they're smart, they're pragmatic, et cetera and so forth.

The 3,000 list of -- the 3,000 chemicals in the list have ramifications far beyond these regulations. They'll have unequal impact because as was mentioned earlier, larger companies can do more with that list than

smaller companies. But I think at the end of the day we all have to be thinking about, do companies know what's in their products, what's in their supply chains? If not, why not? If there are chemicals in there that are carcinogens, mutagens, reproductive toxicants, et cetera, this issue of potency, unequal potency aside. Would companies prefer to have those in their, those chemicals in their products if they knew they were there or would they like to get rid of them? And would they like to see mechanisms put into place to generate the information so that they can make more informed decisions and, in fact, drive their supply chains.

The function of these regulations are important far beyond whether or not one or two or five or ten priority products are selected at the end of the day. And Kelly has arguably given the starting point for what those priority products are.

But keep in mind that what these things should be doing is driving systematic substitution outside, outside the realm of government. With the big players. Some of them have already been mentioned. With the big players saying gee, do we have these 3,000 chemicals of concern in our products, in our supply chains? Are our suppliers telling us about them and what should we be doing about them in terms of getting rid of them?

And in a lot of cases it is those larger producers

who themselves can apply their own knowledge about Chemical X being more worrisome than Chemical Y. To say to their suppliers, these are our priorities for eliminating these chemicals. So this is more philosophical than pragmatic going through to line 29. Yes, I'm a reader of regulations too. But I just wanted to make sure that we don't lose track, don't lose the focus on the bigger implications of what we're doing here.

CO-CHAIR CARROLL: Thank you, Richard. I have Ken and Julie.

CO-CHAIR GEISER: Given that we're okay on time here let me step back a minute and follow up on what Rich just said and others about the bigger picture and just go back to the way that I think about this, given, sort of three years of struggling over this law. I never felt like the law was well-worded. But it left us with a tremendous challenge and opportunity to try to create something really pretty innovative.

And thank you, Michael, for going to Europe and talking about the leadership role that this is playing. Because I actually think it is. I think what we see sort of clumsily framed in the law but now I think well-done by the Department in trying to make the real innovation in this law possible is, first of all, for really a first big time we see a connection between chemicals and products. And the

way of looking at this is from the product point of view but allowing the chemicals to drive the selection of products so that there is a linkage there. But it means that for a state like California with a big market to actually beginning to go after products as a way to think about chemicals.

For, you know, 30-40 years we have been working on chemicals as if they existed in some abstract way and we could simply regulate or standard them out. But this was a chance to really look at the products themselves and to pull in those who manufacture, those who sell and those who import products. The people who actually have a big investment in, quote, "the safety of those products." Because that's what they think their consumers really want. So for me a big first step was seeing that as an innovation.

Now on the list itself. The list is 3,000. Maybe it is bigger. Maybe Dawn is right, maybe it's going to be bigger than that. It does -- I think we've heard the rationale for having a big list. But I'm hoping that we leave the option as the program matures and develops over the next decade, that we can begin to do some kind of segmentation of that list. That we can revisit that list and begin to maybe prioritize some things in that list.

We no longer have the chemicals of consideration and things like that as a background but maybe we need to

figure out some way to do that that gives the market even better indication than we do with this big, broad sweep of a list. The broad sweep of a list is necessary to get us going but I think that we ought to respect that we maybe want to come back and look at that.

The second thing is the connection between the list, the chemicals list, and the products list is still a little tenuous in my mind. I like the fact that it's open and flexible, it gives us a great way to think about the products, but I would add one more criteria in here. And I don't know if we do this in the regulation or maybe it's just done maybe as a way to think about it.

And that is, it is likely that we will use, we will identify maybe three to five products a year, or at least the first year. But the issue might be that that's a pretty slow chipping away at products. If we do three to five and maybe another three maybe a couple of years later and then another we're going to end up with ten in so many years. You know, given there's thousands and thousands of products out there and many, many to worry about, we want to use our selection process as judiciously as we can to not only work with those who actually supply those products but actually drive the market itself as well.

And therefore I would suggest that we think about those products as kind of sentinel products. Products that

have leverage in specific product mixes. Such that by going after that kind of chemical product issue we actually open up a lot of other suppliers of products to think about their products, even though we're not addressing those products. To sort of think about a sentinel kind of quality. Is this product going to have a lot of leverage on an industry or a retail system or something like that. Such that it really does what the list does but now with the products too, is another way to think about it.

And then there's the alternatives assessment. And the alternatives assessment is the fact that we link chemicals and products with alternatives assessment. I frankly, I know I get into dangerous turf here, but without risk assessment is a just amazing big leap. We know that risk assessment has brought us to a certain level where we have ended up doing a lot of great science based on risk assessment. But it has not been the approach that gets us to products.

And it seems to me that what we are doing here is making that link without the traditional, logical risk assessment as part of it. We are still keeping exposure in there, which I think is really important. But we are not tying ourselves up into something that is so out of the view of the public or so beyond the capacities of a normal product manufacturer or whatever that it stays right there

with looking at a substitution that is an engineering/ designer question and doesn't get us into a lot of toxicologists worrying about things.

So I think that using alternatives assessment as it moved forward has been a great piece of this and I really applaud the fact that we streamlined this down. We are the first state to actually try to do this in legislation. We are definitely out there on the forefront of this. How we shape this will shape the way other states think about this and we'll also potentially shape the way other governments think about this.

So I think we are legitimizing and concretizing a way to think about a new tool that has tremendous capacity, not in the old science community but in the new development of entrepreneurship and innovation and things like that. Which I think is really, really smart and good.

The part that's sort of -- you notice we are not even talking very much about, is the regulatory response part. Maybe that's because it's so old hat. We all kind of know how to do that. It' been around for years, we know -- we're pretty good at that. And maybe that's wise just to leave that alone as it is for the moment. And I think that's probably fine. I don't have much problem with that.

I will have a few more comments about assessors and accreditation later but -- I still think it's a problem

-- but basically a lot of applause for this. I think -- and it's not just applause because I think we have gone over a hurdle we couldn't get over a year ago. We are now getting over that hurdle. But also because I think getting over this hurdle sets not only California forward, it sets all of us forward.

CO-CHAIR CARROLL: Thank you, Ken. I have Julie. Meg, you want a second comment?

PANEL MEMBER SCHWARZMAN: It's tiny.

CO-CHAIR CARROLL: Okay, very good. Julie and then Meg and then we're done.

PANEL MEMBER SCHOENUNG: I'd like to echo all the accolades for all the work that's been done and all the positive direction. I just have two very short comments in response to previous speakers so I wanted to get them in now rather than later. And it's really just about semantics of wording.

Michael brought up the de minimis for the assembled products. And I don't know what the right wording is for that. I like the word "cumulative" in there but I think you need to be careful because you have a lot of key words in that sentence. You have "component," you have product," you have "each," you have "all COCs."

I mean, when I tried to read it again and again I was like, I'm not sure how you would aggregate this. What

cumulative of what we're talking about. So I think you need to be careful about the language there and the fact that substances might be included in materials like alloys and composites and things is more complicated than a formulated system where your chemicals are adding together.

The other is just a quick comment in response to Joe's comment about nano materials. Again I would suggest a word of caution in that nano materials is too comprehensive of a word, I believe. Because there are nano materials that have nano structures to them that are not nano metric in size. And so you can get metal ceramics that would be classified as nano materials but have no additional concern for exposure or potential risk.

So nano particles, nano powders, something that really designates the size dimension of the product, of the substance in the product. Even within the scientific community I have this debate with my colleagues all the time. Nano materials is a very, very, very broad term and you need to be very careful about how you utilize that, if you choose to.

CHIEF DEPUTY DIRECTOR MADRIAGO: Let me say something very, very quickly. It was not our intent to exclude nano materials, however you define them. So we will go back with our scientists and make sure that our definition is --

CO-CHAIR CARROLL: Thank you, both. Meg, you get the last word.

PANEL MEMBER SCHWARZMAN: This is, again, just picking up with a specific. Taking off on Ken's more general idea that applauds this move towards alternatives assessment as a work-around, in a sense, to some of the morass that we found ourselves in as a society based around risk assessment and the dueling science that gets involved in that.

We can talk about this a little bit more if it comes up but I wanted to take the opportunity to flag a hitch that I saw in the regulation with regard -- that I see impeding that. Step away from the risk assessment quagmire. And that is in a couple of places of prioritization there is a criterion for prioritization that talks about exposures in quantities sufficient to produce a certain health effect.

And that to me is -- that could grind the entire thing to a halt and it could move it in a direction that we were precisely trying to get away from. And so I understand the intent there, which is to not just sweep the entire universe in. That any, you know, tiny exposure of something that has a known threshold or whatever. We could get into the technical details there.

But, you know, as a historical point, 30 years ago the level of mercury that was assumed to be -- that was by

science known to be associated with an adverse health outcome was 1,000-fold higher than what we know is associated with health outcomes now. So that's 30 years of significant levels of intellectual impairment that are the result of mercury exposures that we thought were safe. Right? So there's so many examples of that.

And we have to figure out some way to get at that issue of trying to make sure that we're staying within sort of reasonable bounds of exposures without getting stuck in a way that I think that language will cause us to get stuck. We can think about that some more.

CO-CHAIR CARROLL: Very good, thank you, Meg.

That brings us to the end of this session and it's time for lunch. We will convene again at 1:35. At that time we'll talk about Question 1, so you can be thinking about that over the course of, over the course of your lunch. We'll have about an hour and a half session on that. So I will see you back here at approximately 1:35, thank you.

(Off the record at 12:32 p.m.

for a lunch break.)

AFTERNOON SESSION

CO-CHAIR GEISER: Well I hope everyone had a good lunch. We are back for the remainder of the afternoon.

This afternoon we will take up Questions 1 and 2 as outlined by Odette earlier. We will try to spend about an hour and a half on each question and we will take a break sort of where it seems appropriate there. We have left a little time toward the end of the day to sort of summarize things and for any remaining comments. We're going to try to close out by about 5:00.

Just maybe a quick note on that. How many of you are going to try to come to dinner together with us later?

(Show of hands.)

CO-CHAIR GEISER: A lot of you, okay. Great, good, excellent, thank you. Thank you for letting us know.

Tomorrow we will start at, we start at 8:30. Yes, we start at 8:30. We're going to take up Question 3 and there will be still time for an overall general discussion after a break tomorrow before we try to break, and we'll try to break by noon tomorrow.

Well that puts us up to Question 1 here. If you do have the little sheet that Odette passed out it's this one that does have the lists of lists on it that are the lists that are discussed. The so-called 22 lists, authoritative lists. You might want to pull that out so

that you're reminded of what the lists are that we'll be focusing on here.

Now during our earlier work in the spring we did take this set of questions up quite extensively. How to think about the construction of the chemicals of concern list. And I think that the Department got a reasonable amount of input from those phone calls, those conference calls.

What the current draft proposes is a sort of rapid process for constructing the central list of chemicals of concern and projects that that list will be some 3,000 chemicals assembled from these 22 lists.

We are being asked specifically to focus on this construction process and to give advice There are kind of in my mind sort of three questions. One which is just to take a look at that decision that has been made by the Department about assembling a large list of chemicals of concern and we heard the justification for it. One is to create some kind of message to the market, another was to get started efficiently, a third was to identify substances that would be sort of low candidates for alternatives later in the alternatives assessment process. And I think those were interesting.

But I think the first question, the first thing to think about in your mind, does it make sense this idea of a

large list of some 3,000 chemicals as the list? A part of that is also how is that list constructed? Is the manner in which this list is constructed around these 22 substances, lists of chemicals, they are pretty diverse. Some are government lists -- many are government lists actually. There are some scientific lists, there are some other kinds of lists.

They're clearly not all assembled for the same reasons. So there's some diverse reasons why these lists exist. Does it make sense to merge these? Are there outliers? Are there some of these lists that don't make as much sense? If you were being asked to defend the construction of this central list where do you think the weakest link in the lists are? Are there lists that are not being addressed here that might be more appropriate that you know of? So the second part of this question really has to do with the construction itself.

And the third question is just a speculative one which is, do you see what euphemistically could be called, unforeseen consequences of assembling the list in this manner?

So we'll spend about an hour and a half or until we saturate the topic, essentially. And in all fairness, it's not like we haven't talked about this before so don't feel like you need to go back to ground zero here. But you

are very eager. Look at that, all right. So we will start. And if you don't mind I think I'll just start back there and come around. Julia, would you like to lead us off?

PANEL MEMBER QUINT: On the idea of the list. I am supportive in general of lists, primarily because I like the idea of taking advantage of work that has already been done rather than, you know, recreating the wheel, so to speak.

But I think it's really important how you construct the list. The concern I have about the 22 lists that are in the regulation is what they omit. That I think some hazard traits and toxicological end points and environmental end points that I think are important that are not captured by this list.

And some of that has to do with the fact that no list exists for some things that I think are really important. Respiratory sensitizers is one of them. Asthma is a big problem and, you know, especially amongst children and some products can contribute or cause new asthma or exacerbate asthma. So there is no list that I know of that has respiratory sensitizers on it so that isn't captured.

Dermal sensitization, especially for products that you apply to the body, which is one of our target emphases in this in terms of looking for products, that's not captured by a list although one could be developed.

Neurodevelopmental toxicants. It's not captured by this list.

I am opposed to having the Grandjean & Landrigan list included in this because in reading that paper, that's a list of identified neurotoxicants that is derived from -- it's acute neurotoxicants mainly from suicides and things like that. So, you know, it doesn't capture the types -- and it ignores -- and according to the authors it does not capture known animal data on neurodevelopmental toxicants and it doesn't capture chronic neurotoxicants. So if we use that list we will be limiting ourselves to human data and human data that in some respects I don't think is necessarily relevant in terms of how we have constructed -- what we get from the other lists in terms of an emphasis on chronic toxicity and use of animal data.

And the other thing that I think is missing that I can't find if it's there is ambient ozone. A list that captures toxicants that, you know, contribute to an ambient ozone. Also ozone depletion. That isn't captured. In fact there is very little about air pollution as a hazard trait captured on this list.

So I think while lists are, you know, in general are okay, I think you really have to go back to looking at the hazard traits as they apply to sensitive populations and how we prioritize those and make sure that we are capturing

the things that we consider important on these lists.

And also in terms of there seems to be a little bit of a difference between authoritative organizations as defined in the hazard trait regulation and how we're thinking about these sources. In the informal draft we have in front of us there is a reference to authoritative bodies. I'm not sure if that is the same thing as authoritative organizations.

In the hazard trait regulation I like the way they define authoritative organizations because they actually list evidence sources that are used by government agencies when they are doing, identifying things for public health action. So that these tend to be more vetted sources. They wouldn't be -- the Grandjean & Landrigan list would not be necessarily included in something like that. So that's my take on it.

CO-CHAIR GEISER: Thank you. Jae. Is it Jae or Mike?

PANEL MEMBER CHOI: Mike.

CO-CHAIR GEISER: I'm sorry, Mike.

PANEL MEMBER WILSON: Thank you, Chair. And I think this really picks up on Julia's point. But first I just want to reiterate that, you know, it's tempting to think of the idea of a list of lists as a fairly simple idea. That one could simply go to the web and create this

list of lists and then you have this master spread sheet and there you go.

But it turns out, as you know, this list of lists really as a database, a searchable database, has never been constructed except by consulting firms and so forth. It hasn't been constructed and placed into the public domain. It's an important process that is going on here and it's going to provide, again, really important information to the market and to businesses. Giving them a tool, I think.

I would like to reiterate a couple of points that Julia made. One was on the question of asthmagens. My understanding is that the Association of Occupational and Environmental Clinics has developed what is a reasonably authoritative list of 303 asthmagens that I think they classify both as sensitizers and irritants. That's an important one for occupational exposures in particular.

And the occupational health branch, the surveillance program within that branch is tracking work-related and work-exacerbated asthma. And it continues to be a substantial burden of disease, expensive and debilitating in California, so it's worth getting a better handle on that.

The second is also in the occupational setting, the NIOSH occupational set of carcinogens. It's only 146 substances but these are -- there's really no dispute any

further about those but they are specific to occupational settings.

And then there are two additional ones. One is the REACH substances of very high concern candidate list. Again, this is in sort of the interest of harmonization. It makes sense to track what's happening in the European Union and not subject companies to differing kinds of criteria and so forth.

And then finally the other addition that I would recommend is the state's own biomonitoring program. California has, I think, the nation's preeminent biomonitoring program in collaboration with CDC and is conducting studies and biomonitoring work in identifying substances of concern that are unique to California. To our agricultural industry as well as to products that are specific to California for various regulatory reasons and so forth. But it's housed both at OEHHA and the Department of Public Health. Very much worth leveraging and placing into this context. So thank you, Chair.

CO-CHAIR GEISER: Thank you, Mike. George.

PANEL MEMBER DASTON: Thanks, Ken. I guess I have a couple of topics but let me talk about the lists first. I guess to be blunt, I think the list of lists is over-reaching. You know, there are a number of entries onto the list of lists that would never be considered to be from

authoritative bodies. And so I think, you know, as you go through this, I think Julia has already mentioned that the Grandjean & Landrigan article, in no way would that ever be considered to be from an authoritative body and would be disputed, as Julia did, by people who understand the toxicology.

You know, things like the OSPAR list of substances of possible concern. The NTP CERHR reports, which, you know, cannot be taken by themselves as evidence that something is a reproductive toxicant because what they do is they evaluate whether it is or not and basically give it a score as whether they have concern or not. So all of these things need to be evaluated.

And I do understand the reason for including some of these things and it is to, I think, expand out beyond, you know, the lists of CMRs to other end points that individuals around the table have indicated are of concern and I don't dispute that at all. But I think that, you know, in order to make the process credible and scientifically robust I think we have to be very careful about what lists we use.

I think that if we started with the ones that are indisputably from authoritative bodies there would still be, at worst, several hundred chemicals on the list. And so I think it would fulfill your interest in having a large list

of which to work from but wouldn't be such that you would end up, you know, having a lot of disputes as to whether the list was correct or not.

I think that over time, and particularly with help from some of your sister agencies, I can think of many ways in which one could create a list that would be authoritative in nature for those other kinds of end points. But I wouldn't necessarily, because you don't need to to move forward right now, include all of these lists that are of varying quality. So that's just my comment about, about lists.

I don't know, Ken, tell me if you want me to hold my peace, but there are two other issues in the chemicals area, I think you're in the chemicals area, that I wanted to talk about. And I can stop and talk about them later. But they're about the de minimis decision and then about this business of cumulative assessment of things with the same hazard traits. Should I hold on those or do you want me to put them on the table now?

CO-CHAIR GEISER: Why don't you hold on those and we'll try to take them up towards the -- let's see if we can stay --

PANEL MEMBER DASTON: Cool.

CO-CHAIR GEISER: -- so that the conversation has a consistency. But let's hold, George, and I'll come back

to you on it. Yes, Ann.

PANEL MEMBER BLAKE: Since I haven't yet added to the accolades for this morning I would just like to do that. Well done navigating some very tricky conversations in a fabulous way. So great work for that.

I would like to echo a lot of the comments that have been made so far down this end of the table about lists. I know you had to start somewhere and this is a great start. And we could quibble about lists, and in fact I will quibble about some of them and agree with some of my colleagues here, but drawing the line here was a very reasonable approach.

I do share the same concerns about the Grandjean & Landrigan list in that we tried to use it for consumer products in GoodGuide and it was very troubling to do that; it was not all that relevant. So that may be one -- I know why you included it, because there are so few choices for good neurotox data. But I echo what Julia and George have said that there may be other ways around that.

I would also echo using the AOAC list of respiratory sensitizers. That's a great place to start and I would echo adding that.

Several of the things that I like. I do appreciate the balance of hazard and exposure and proxies for exposure that you've included in this list. And I also

am thankful that even though there are some pieces that maybe have been omitted, as Julia and Mike have mentioned, that they environmental end points have been more broadly included. And I know Kelly will probably have some comments to add to that so I will let her do that.

But I think the bigger contribution that has not been highlighted is that what you have done here specifically in this cheat sheet is that you have highlighted the underlying criteria for the reasons for which those lists have been included and I think that's a really key piece that has been key here.

So we have been talking a lot about the 3,000 chemicals but I think the more relevant message that is being sent to the market and more broadly is that these are the underlying criteria that are being considered as descriptors for our chemicals of concern.

And I don't know if you meant that to be implicit or explicit. I had some concerns -- I heard some concerns this morning about process and inadequate process. Perhaps you may want to make it more explicit why you chose these particular criteria. And that comes with a caution to me is that you've got -- by selecting and highlighting these criteria you've got an inherent weighting. So just a caution to that. It may be entirely appropriate that you've chosen as a regulatory agency with a particular mission that

you have these end points but to make that explicit in your choices.

And then to Ken's question about consequences. I think Mike Wilson spoke this morning about impacts on investors. And I can tell you that the same list of substances of very high concern, which goes more broadly than the REACH-identified list, is already being used by investors in Europe to identify chemically-intensive industries that are dependant on those chemicals that are identified as substances of very high concern. And I would assume that the list of 3,000 chemicals and/or the criteria underlying them from California would have the same effect. So that's a positive consequence.

CO-CHAIR GEISER: Thank you, Ann. Bill.

CO-CHAIR CARROLL: Thank you, Chair. In general a list of lists could be a good thing. Particularly from my perspective, it avoids having to start from first principles on everything. And one of the things that I was a bit concerned about in our previous processes was that we would wind up with a rather small list of chemicals from which we'd started from first principles. And particularly if there were things that were not generally recognized as being of concern. That immediate de-selection pressure in an unfortunate way could have taken place. And I have a little more to say about that later on.

But in the end if you are going to use a list of lists there are a couple of things that I think should be considered. I am not going to go re-plow the ground as many of my colleagues have done; I want to augment that ground just a little bit.

First of all it's a matter of what constitutes an authoritative list. And perhaps it would be good to have a bit more in the way of ground rules as to how something gets on the list as being authoritative. What sort of gates it has to pass in order, in order to be there.

The second, the second thing that's worth considering is to consider lists where you have already had the opportunity for, at the very least, public comment and submission of data above and beyond what was considered in the construction of the list itself. There are some of these lists that are very well vetted over time and those would pass that screen for me. There are some, however, that perhaps as the Grandjean & Landrigan article, which are mainly based on one publication, that frankly doesn't pass that kind of, that kind of sieve for me and I think that's something that's worth considering.

And second, and you heard a little bit about this earlier today, is whether once something is on the list of lists, are all chemicals created equal once they're through that screen. And clearly you could take one to two

approaches. You could say, in is in and anything on there is fair game. Or you can say, we probably now ought to sieve these down further and see if there are some, either because of their hazard traits or because of their hazard traits plus some of the other exposure considerations, ought to percolate their way up to the top of the list.

So it's those two things. What constitutes an authoritative list; and second, will there be a prioritization on the list of lists once it's constructed? Thank you, Chair.

CO-CHAIR GEISER: Kelly.

PANEL MEMBER MORAN: Thank you, Chair. I really appreciate the opportunity to provide some advice on this topic.

Just as context. When I look at the listings I actually do see the lists as prioritization of all of the chemicals that are in commerce. We're only talking about a few percent of them. And I personally actually don't have a sense for of 100,000 chemicals in commerce how many of them are potentially hazardous. Is it 10 percent of those, is it 20 percent, is it 5? There's some percentage that's hazardous and the rest aren't. You know, ones that really rise to the top as having harm. If we're talking about some several thousand chemicals here we're only talking about a few percent. So that does seem to me like inherently a

pretty strong prioritization.

And further I think that when we start prioritizing further we really need to be considering things other than just the hazards and that's been brought up many times. And a great example of that is the old copper brake pad story that I always get teased about.

(Laughter.)

But it's a really great example. If you're thinking about that, if you're thinking about things that are harmful in the world the first thing that floats up in your brain is not copper because it's not typically harmful for people. But if you're a juvenile salmonid that is trying to avoid predators, copper is extremely important. You could live or die based on a few nanograms, or micrograms actually, per liter of copper.

So it's a little harder to do that prioritization once you get the chemicals and you actually want to think about all the other considerations that are there. So my thought in this is that we are actually prioritizing. And there was some in here for further prioritizing in the context of exposures as the law directs through the product systems. So my sense is we are actually doing the things that people are asking that the law be done. And if you go back and think about all that you can decide if you feel that way too. But that's kind of how I was thinking about

it.

So now for some comments. Since I'm the person everyone looks to to talk about the environment other than humans. It's always intensely disappointing to see how so few lists refer to environmental end points. In fact, there's very few here. But the problem is I'm sure it's not for want of trying on the part of the Department. There aren't people out there creating lists of chemicals that are harmful to wildlife and fish in the same way there are people who are creating lists that are harmful to people. So it's a really difficult exercise.

So I'm lamenting that and at the same time trying to think of, are there other lists out there. And the one that immediately leapt out at me is that US EPA has developed water quality criteria for aquatic life, for pollutants that are not on the list of priority pollutants. Which is --

The two water lists here are very backwards-looking. The priority pollutants list from the Clean Water Act is something that was established when the Clean Water Act was written and we were looking at all the problems behind us at that point and the ones we wanted to clean up. And the same thing with the 303(d) list. That's a list of problems that were already existing at the level and for the length of time that we have been able to define them

regulatorily and we're spending millions of dollars on them.

So it would be awful to have a list that's looking forward. Other than the water quality criteria -- the US EPA has developed water quality criteria for other chemicals so it's a little more forward looking. I would suggest that consultation with the Water Board and Fish and Game -- the US Fish and Wildlife Service, particularly NOAA Fisheries, has also done a lot of thinking about this. And I do not know if there are lists out there, have been looking for these. But we may be able to get some help from those resource agencies instead of the human health agencies by bringing in at this point and having some consultation with them. We might be able to make sure we've covered those.

Then I started thinking about, well what is it that makes something that defines a problem, strictly a water pollution or a wildlife problem. We usually find those from toxicity. So something is dying, something is malformed, something is not reproducing, it's some other kind of thing, and we go out there and we try to figure out what those toxicants are.

And then that made me go back and look at the lists that are here and say, well how many problems do I know of that I have seen in my career that involved chemicals that are not on these lists? And the answer is, not that many. It's the same chemicals a lot of the time.

That made me feel better about the lists.

The couple that I came to, one of them that I'm not sure would be captured on this list is nonylphenol. And that's one for which there is a fairly new water quality criterion at the federal level.

Another one were some of the nanochemicals and particularly the carbon nano tubes. So nano-silver would be caught because silver is on the priority pollutants list but nano-carbon wouldn't necessarily be caught. So there may be a few examples like that. I'm not sure if there is necessarily a way of getting at those.

And that leads me to my next thought, which is that at some level a list of lists like this is going to be imperfect and I'm seeing that it's going to be particularly imperfect when it comes to wildlife and environmental and non-human endpoints. And that's why I think the petition process is so important and I view this as a hand-in-hand kind of thing.

And my caution on that is that it is going to be really important that the Department not have to oversee a chemical by chemical debate for those additions. So I'm a little nervous about how that works with the petition process. But it may be that that's just what we're struck with for this initial round until we go to another way.

And perhaps one of the things that DTSC needs to

do as part of Cal/EPA is be going to its sister agencies and say, can you give us a reliable list that has been vetted through public comment and peer review of things that you think are missing.

So the final thing, a more technical point, is that I'm not clear when I read this -- and I could ask this as a question but I think I might just make it as a comment to move us along. There's two kinds of chemicals that I'm not sure are captured here in these lists and I think it's really important to capture.

One is that sometimes the chemical in the product is not the actual pollutant of concern. A good example of that is nonylphenol. So that comes from nonylphenol ethoxylates that were put into products. And then when they go through sewage treatment plants and get out in the water they're degrading to nonylphenol, so your pollutant of concern would be nonylphenol. But you need to be sure that the law is structured so that you can solve the nonylphenol water pollution problem by capturing the product, the chemicals in the products that then degrade to the pollutant of concern.

And this has been a really big problem in pesticides so I really don't want to see DTSC repeat that mistake in its regulatory framework because we are still dealing with that with DDT and triphenyl and endoxycopre

(phonetic). We're still dealing with just a whole list of pesticides. So it's a really big gap over there that I don't want to see you do here.

And then the other one is that there are often, like particularly for metals where this is most common. A metal is a problem. In copper in brake pads we actually had a whole discussion about whether the legislation was for the copper or all the copper and compounds and it meant "and compounds."

I have been working on this with zinc, which is a really great example. Zinc metal is what's listed in the priority pollutants list in the priority pollutants list in the Clean Water Act. But in commerce that's sold as zinc metal. It's sold in a variety of alloys. Zinc oxide is a very common compound in commerce. And there's a variety, there's even organo-zinc compounds like zinc pyrithione that commonly appear in commerce.

So if DTSC only refers to the list and says, oh, it's only the item on the list and not the other chemicals that maintain it, as a chemist you're missing all those elements. As a formulator you might just switch to the organo-zinc instead of the metallic zinc. Or say, I'll take an alloy with zinc instead of the metallic zinc. And that would be completely missing the point. So that would be a great example of regrettable substitutions that we don't

want to regret. So sorry for taking so long. Thank you.

CO-CHAIR GEISER: Very good, thank you. Dale.

PANEL MEMBER JOHNSON: Yeah. First of all I was, I was not a fan of the 3,000 compounds, chemicals of concern right off the bat. I was not a fan of that. I was more in favor -- you know, I have looked at this over time, I have listened to everybody talking about this.

Putting these lists together is not a simple job. It's not a simple job to come up with a list of compounds. I have students that have been doing this for the last seven years. There are commercial databases you can go to, you can look at various types of things, but what you will find is that there are very one-point connections between various types of toxicity end points, chemicals and so forth that will show up in databases and then they will be carried on into other lists as something that could be a hazard or, you know, could be toxic and so forth.

So the first point I would make on a list -- and I don't like the term "list of lists" because there's a difference in the series of lists. And number one is, there are lists where the information is not verified, it's taken from anther list. And over time once that gets passed from one list to another list to another list, all of a sudden you have got something that connects as a hazard but in fact it's a single point that occurred in one publication

somewhere.

From a toxicology standpoint what you do know is that all of the toxicology studies that are run, this is everything. Every toxicology study that's run for all of these hazard traits, reproductive traits and so forth, are run to actually have a high dose that induces the toxicity. And then you back off from that, you make some kind of a risk evaluation based on the species of animal that the toxicity was developed in. But from a list over time you can actually get that information that relates to this very high dose toxicity. Then it would be carried on into another list and really it's not the end points you're actually looking for.

So the first point is, if you're going to use a list the list has to be verified. It can't come from a secondary source. Because the last thing you want to do is put in to this particular, you know, this regulation -- you do not want to put in something that's secondary, coming from a secondary list. Because that will end up in some very severe -- I would say that's going to end up in a lot of, possibly even litigation in terms of that. So it has to come from a verified list.

What are those lists? Well, even some of the EPA lists, you know, the US EPA lists, are not verified. They're secondary lists. I have, I have been astounded to

look at that but my students have found those cases. And I'll just leave it at that because I've listened to, you know, this list/that list. But they have to come from a verified list.

The second thing is, one of the consequence that will occur from the chemicals of concern list right up from within a very short period of time, and I mentioned this last week at this conference. And the reason I mentioned this, I have had two students to bring this up to me already. Once the lists appear and then I turn that into a website where people -- I'll use other sources of information of what chemicals are in what product, what consumer products and everything else. So that consumers then an have a guide to not choose that product.

So then the question comes up, well that's fine, you know, maybe that works and so forth. But what they're choosing is another product that doesn't have any information on it. So it's kind of defeating the process.

Now that's probably just a short window of time because I think the positive parts of it outweigh that. But that is a window of time where that actually will occur. And I have two students that probably will do that within a month of the, of the lists because I can't control students.

(Laughter.)

And so the 3,000 chemicals of concern on the front

end. You know, this was always kind of my concern that it would be based on information that may or may not be relevant in terms of hazards. Because, you know, as a toxicologist, everything is hazardous if you jack up the dose far enough to make it hazardous. So how would you actually do that?

I have listened to, you know, I've listened to the argument as to does this drive the marketplace in, you know, kind of a positive way? That's a good argument, I like that argument, I mean, that's the argument that you listen to. I happen to be an entrepreneur. And the argument is that something is going to be there to create something else in the future and it's always a good argument. You know, it's kind of like sitting there thinking, maybe this is the start of the Internet and Al Gore will show up and then we'll be okay.

Do you start with two to five products and so forth? I think that's a good thing. And I think what's going to happen from that. That will stimulate a lot of other stuff that's going to go on. So I see it as something that's actually going to blossom over time. And it doesn't necessarily have to be the resources coming from the agencies because I think it's going to happen. I think this process is going to happen. So I'll just leave it as the list that you're going to use has to be verified.

CO-CHAIR GEISER: Dale, this experience that you've had with your students, is it creating a list and is it worth the Department -- I mean, is it possible for the Department to see what you're learning from that?

PANEL MEMBER JOHNSON: Yes and no. Because what most of the students are more interested in is how to link a chemical into a gene or a mutation of a gene that links to a certain disease. And so you can get into that kind of information. You can come up with lists of -- I will tell you there's more than a million chemicals that could be linked to a gene, could be linked to this. Actually there's public databases that allow you to do that. But is that information absolutely relevant in terms of a hazard to, you know, human health and the environment? It's hard to say.

CO-CHAIR GEISER: Thank you. Bob.

PANEL MEMBER PEOPLES: So the first thing I'd like to do is ask a question about maybe process. And that is -- related to the reg. And that is, once the formal regulations are promulgated are they locked in stone or is there a reasonable or rational process to evolve them based on feedback and learning?

CHIEF DEPUTY DIRECTOR MADRIAGO: Regulations are never locked in stone. However -- And frequently they are changed through the process of learning because you never get them perfect. So it's quite possible we will go back

and revise these regulations using a similar process to what we're using now. You know, the law does require we go through a certain structured process and depending on what we're doing we may or may not need input from the Panel.

PANEL MEMBER PEOPLES: Okay, we'll thank you. So that's, that was helpful. And that's sort of the context for where I wanted to make my observations.

So there's a lot of very smart people around this table and I really respect the perspectives and the expertise that's brought to the table. My comments are going to be pretty much pragmatically focused here and fairly short.

My concern is that we can get into paralysis by analysis and these things could quickly exponentially grow to be completely unwieldy. One of the, one of the consequences of that is business gets very uncomfortable, business is unwilling to make any commitments and therefore a product risk doesn't get made going forward.

So, you know, I believe in the idea of the list. And I think the lists are useful because they help define the boundary conditions that let people say, okay, now I know what the rules of the game are, I can move forward and implement. So if we can get to that point I think it's important. To get to that point we need to somehow figure out how to draw a line on what is and is not included in

these lists and the idea of these authoritative sources of all that have been discussed I think is an important component of that.

As I look at the lists in this document, I am not familiar with all of them. Nor should I be nor am I ever going to go look them up personally.

However, for the people that are going to have to live with this, one of the things that I learned in our standards development work for NSF 140 in particular is the idea of having a link in one place to all of those sources so that if somebody is working these documents they could easily click on and get to those resources. I've spent a lot of time and frustration trying to figure exactly what list are we talking about, what version of that list are we talking about and how do I get my hands on that list that we're talking about. So there's another pragmatic element that goes along with this as well.

At the end of the day, again, I think the real value of this initiative is going to come from the fact that you're going to identify the first round of the top list of chemicals of concern and the products that create -- contain them. And if it's 100, if it's 200, if it's 500, whatever it is, we need to draw that line in sand. We can't have 3,000. You can't tackle 10,000 or half-a-million all at one time because we'll get stuck in this paralysis by analysis.

So using the, using criteria like the nine specific hazard traits to focus in on key chemicals on page 8 of the Summary I think is going to be very valuable going forward. Business will benefit and I believe will cooperate more readily if there is this kind of rational guidance and not this belief that this is going to be every standing list for which they can't get their minds around. I think that's probably where I'll stop.

CO-CHAIR GEISER: Thank you. Meg.

PANEL MEMBER SCHWARZMAN: Thanks. I like I getting to go after people because they raise points and I find out information.

Just speaking generally. I want to keep in mind that a list of chemicals of concern is just that. It's not necessarily that there -- I think a list of chemicals of concern should be broader than NTP-known carcinogens. It's not the worst thing if the list also includes possible carcinogens. Because it's a fairly narrow scope of a regulation as a goal if wheat we're trying to do is move the products that contain possible carcinogens instead of known carcinogens. That's, I think, narrower than this three years of effort on everybody's part, justifies. And so I want to put in a plug for keeping a broad list of chemicals of concern because then, step-wise, processes are taken from there.

And I think the main -- I hear everybody's hesitations about, is any particular one of these lists the definitive one, is it authoritative enough? And in my mind the answer to that is being very, very transparent about the origin of the list, it's defining guidelines and knowing the limitations of that list.

And potentially instead of -- I don't mean to endorse the neurotoxicant Grandjean & Landrigan paper but do we necessarily want to throw out something if it's not the definitive treatment? That may not be a useful list of neurotoxicants. But if don't propose it to take as the definitive list of neurotoxicants it may yet contain helpful information. So that's all I mean is we should know the limitations of the lists, take from them what we can, but make it very clear what we haven't covered in those lists.

A specific list that I do really want to advocate for that's in here but George suggested removing is the NTP OHAT list, which used to be CERHR. I guess OHAT is easier to say. And that's the one that -- one of the reasons I think it's important is because it's one of the few sources of true, of information about true developmental toxicants. And by that I mean, not the substances that cause birth defects but substances that act during development to have different effects than if we're exposed as adults.

And that's one of the few places where some of

those compounds are picked up and that's particularly a set of criteria that's called out in the regulations of how can we identify compounds that might have different effects on children or if women are exposed during pregnancy. And this is one of the ways to start identifying some of those. So I think that's an important list to continue -- to keep in. And it's okay to choose a subset of it just like you choose Categories 1A and 1B carcinogens or something. You don't include the entire IARC list but you choose where you draw the line.

I want to talk for just a sec about -- you know, there's these lists from authoritative bodies and then there's also the criteria laid out in the regulation about how DTSC makes additions to those lists. And I think it's worth keeping that in mind as we talk about this because anything that we're missing from the lists we're hoping there's a way that the additions, the criteria that are laid out in terms of making additions to the list, should help cover those.

So I think -- like as Kelly talks about the shortcomings in some of the lists that are on here that's inherent for ecotox outcomes, we should look at the criteria for additions and make sure that there are ways there to get in those substances that would be left out or outcomes that would be left out.

And you raise the issue of nonylphenol, which you were worried about being covered, for one thing. And I would just quickly say it's in REACH Annex 17. But even more than that I saw in the prioritization process in the regs that degradation products are called out.

And so I think Kelly's example is just a really good one. That it actually shows some ways that DTSC has already considered and treated some of these issues and that I want to say are good treatments. And they should stay, I guess is my point. So this ability to add to the list provides good flexibility and the petition process I would also support.

There are two technical details that I think need to be corrected. One is it talks about aggregate effects. And I think what you really mean is aggregate exposures. And there's something different that is cumulative effects. And I think both of these are very important to pull out and I'm glad that they were. So it's excellent that the regulations identify the need to account for aggregate exposures, was how I read it. So that's multiple sources of a single chemical and that that can cumulative impacts. And that's excellent right up until the point where it starts talking about mode of action.

So cumulative impacts you think of as -- let's take something that's easier to picture like obesity. There

are cumulative impacts that lead to obesity and they are lack of exercise, bad diet and maybe there's also some genetics -- well definitely genetics and also maybe some environmental exposures that contribute to that. So there's cumulative impacts that lead to this health end point that is obesity.

Each of those factors acts through a different mode of action. And so if you say that to count something, to accumulate something, to add some factors together they have to have the same mode of action, completely negates the effect of calling for looking at cumulative impacts. So you can picture that in obesity. It's much more sort of like eating and exercising stuff.

But particularly -- I mean, at least it's true with how chemicals act. And when you look at endocrine active compounds, you know, you look at -- even if you were to say, the health outcome of interest is something that is a sign of estrogen activity. You can get that through direct estrogenicity or you can get it by blocking androgens. Those are different modes of action. But when you have them together it increases the potential for having that health effect. So that's -- I think the mode of action language needs to come out of there, of having the same mode of action. And it's a few places in the regulation.

The one -- let's see. The one other thing that I

wanted to say because it helps, I think, address some of the concerns that are being raised about lists, is in a sense the -- and I know DTSC knows about this because we talked about our Plum database with them. We started putting some of these ideas to work and testing how we can do it by creating the Plum database. It's a freely accessible online resource; you could pull it up right now. It's plm.berkeley.edu.

And we started putting this, what started as a very simple list of lists project, into a database. And made it searchable through faceted navigation. We have also done a lot of the things in a sense that Dale was calling for, which is going directly to the source of the list.

And for each list that is in there there's a very clear -- so we really focused on the transparency and the clarity of the methodology and very thorough curation of the lists. Including that the chemistry was working. And this found a typographical error in Prop. 65 that had to be addressed and things like that. So very careful curation to make sure that there's fidelity between what's on our database and what's on the list. And really to what it meant, not just, you know, word for word. And live links to everything. And then it's searchable. So I just put in nonylphenol and found it on the REACH Annex 17 list.

The Plum database is not complete; we have been

working on it. It's not fully populated, even with the list that we want to put in. And it's also not a database of chemicals of concern, it's a database that lets you look at what lists are these chemicals on. So since I'm talking about it now I don't want people to misunderstand it. But there are a lot of about pages there that explain how we made the database. You can subscribe to Atom Feeds for updates, you know.

So it's a -- we can talk in a lot more detail and we have already talked some with DTSC folks about all the things that we've learned through doing that. But one of the main things it's taught me is that it's possible to overcome these issues like that Dale is raising about the mistakes that can be made. Like the telephone game of chemical lists, in a way, is what you're talking about and we found ways to work with that.

There was one other point. Oh, I know. Kelly asked how many chemicals of concern might there be? And one shot at that is what Canada did and they created the Domestic Substances List and chose a subset of compounds for which they wanted more information or had some concern and that was 23,000 substances. Now those aren't all going to become chemicals of concern because some of them it's just, they're a little worried and need some more information. But that, I think, helps with the context for what is 3,000

relative to Canada's DSL list of 23,000 relative to the universe of chemicals. Thank you for your patience.

PANEL MEMBER JOHNSON: Can I ask a question? Just real quick.

CO-CHAIR GEISER: Sure.

PANEL MEMBER JOHNSON: When you put out the list will it be in categories or will it e just a list of compounds?

CHIEF DEPUTY DIRECTOR MADRIAGO: So once we adopt the regulations we will, you know, publish officially. We plan to share it before that once we feel confident that they're correct and accurate. But we will plan to list all the chemicals that are captured. And I -- I don't think we finalized exactly the format we're going to have. So I don't know that it will be categories but I would imagine we would have a column that would show the hazard traits associated with that chemical and a column showing the lists that it was listed on or something. Or we might have several different ways we can sort it, which is probably what would be most used.

CO-CHAIR GEISER: What's your point, Dale?

PANEL MEMBER JOHNSON: Hm?

CO-CHAIR GEISER: Is that in anticipation of a question?

PANEL MEMBER JOHNSON: Well, you know, if you have

got a list of 3,000 compounds you would like to know which ones are, you know, right off the bat, which ones are carcinogenicity hazards and which ones are environmental water hazards or whatever.

PANEL MEMBER SCHWARZMAN: Can I chime in for one sec? Because we've done that all on Plum with tags. So the reason for a chemical being listed is included in the database. So you can say, what's listed because it's a carcinogen, and it sorts it immediately. Or

PANEL MEMBER GUTH: And what list it came from?

PANEL MEMBER SCHWARZMAN: What's that?

PANEL MEMBER GUTH: And what list it came from?

PANEL MEMBER SCHWARZMAN: And what list it came from, yes. And then you can click and go to, what does that list use as criteria for carcinogenicity. Because, of course, they're not the same.

CO-CHAIR GEISER: Meg, can you say how many lists the Plum is drawn from at this point and how many chemicals?

PANEL MEMBER SCHWARZMAN: At this point Plum contains 13 lists. But some of the lists that we might prioritize are actually not up there because of technical stuff about how hard they are to get in. Like pulling them off of PDFs and out of NPP monographs. And it's currently about 23,000 chemicals but the majority of that is from the Domestic Substances List. So for example, Annex 17 is

1,000, REACH Annex 17 is 1,000. Some of the others on here. Yes, the Canada DSL is 22,000.

CO-CHAIR GEISER: That's fine.

PANEL MEMBER SCHWARZMAN: The European PBTs is 125.

CO-CHAIR GEISER: Thank you. Michael, do I see you next?

PANEL MEMBER KIRSCHNER: Okay, thank you, Chair. Just a couple of quick points. Mike Wilson mentioned the SCHC list from REACH but that got me thinking about why we would or would not include that list. It's really just a prioritization list itself because all those substances in there are contained in I think, I believe in these other lists here. But they're enriched so there's lots of information on them. Particularly where used it's very interesting. You'll find actually a lot of them are process chemicals so they would tend not to really be in products. But take that for what it's worth.

I think that's about all I had to, actually about all I had to say. Oh, the other thing, yes. Sorry, I don't want to be Columbo here. One more thing.

(Laughter.)

Anyway, these lists change. And particularly, you know, something like the SCHC list changes dramatically every six months. What is the mechanism to deal with the

changes to the underlying lists?

CHIEF DEPUTY DIRECTOR MADRIAGO: Well, under the California Administrative Procedures Act, which governs the adoption of regulations, we are not able to just in the, you know, initial regulations, adopt a list and then say, as things get added to that list they automatically are incorporated into our list. So the way we have this set out in the regulation is that when things are added to these lists and we want to add them to ours we would do so using the public comment and review process.

CO-CHAIR GEISER: Julie.

PANEL MEMBER SCHOENUNG: Well I'd like to just start by saying I also advocate a broader list and I see the values of that. But my specific comments.

One is an echo now of what Bob had commented in terms of the sieves. There's been several people who have said that ultimately within these how do we prioritize the 3,000? And you really already have an initial sieve and that's your de minimis distinction on the nine traits. So whether or not you agree that that's how you want to prioritize the 3,000 chemicals you might want to think about if that's consistent because it's already creating a priority sieve for your decision-making.

The other is just a question on the US EPA TRI. I'm just curious why it only would list the PBTs instead of

the complete list of 500 and some chemicals?

CHIEF DEPUTY DIRECTOR MADRIAGO: Do any of our scientists want to answer that?

DR. WONG: I had to come over here to answer this question because Corey said, you're the one who made me take that off.

(Laughter.)

Well the view -- We were trying to -- again as we looked at these lists, we're trying to use lists in which authoritative bodies have made some particular decision. You may argue, you may all argue with me and disagree with us as to a particular authoritative body.

In the Toxics Release Inventory we did not include the entire list because we felt that many chemicals that were on there, they are simply things that the EPA was looking for and not necessarily making the determination that those chemicals were specifically hazardous to the environment or human health, it was simply an inventory system.

Now maybe my logic on that or our logic on that is wrong. I mean, we're here to get input from all of you. Because I just saw Joe like wake up, he was sleeping there for a moment.

PANEL MEMBER GUTH: I thought it was the Toxics Release Inventory.

DR. WONG: I understand. But again, it's an inventory. And again, we are trying to establish a set of chemicals that we need to focus upon and not every chemical that's out there that's of interest to, you know, everyone. We're just trying to set a priority. We are trying to, in the parlance of warfare, limit our field of fire. So if we are doing it too much let us know, we are happy to hear.

CO-CHAIR GEISER: Julie, you want to finish up?

PANEL MEMBER SCHOENUNG: Lauren Heine is not here today but on behalf of her and her Green Screen approach, we have looked at all the PRI substances and we can't find any that aren't benchmark one or benchmark two. So I think you might want to look at that one more time.

CO-CHAIR GEISER: Thank you, Julie. Tim next.

PANEL MEMBER MALLOY: Thank you. You know, I actually put my card up last, I think, so I don't know if that makes a difference.

CO-CHAIR GEISER: What I'm going to do is -- no, if you don't mind, go ahead.

PANEL MEMBER MALLOY: Okay.

CO-CHAIR GEISER: I'm going to pick up -- I know Jae and Roger and then we'll go back.

PANEL MEMBER MALLOY: Okay, thank you. I just had a few comments. I don't have a lot to say about particular lists but I just wanted to comment on a couple things that

have already been said. And then I had, if it's appropriate at this point, I had a list of potential unintended consequences of this. Are we picking that up now as well?

CO-CHAIR GEISER: Yes.

PANEL MEMBER MALLOY: So in terms of -- I find myself somewhat ambivalent. I see the usefulness of the 3,000 as a way of making this tractable, manageable. Otherwise you're looking at the whole universe of chemicals as your first step and that seems to be, particularly in the resource constraints that you have, that seems to be unmanageable. Three thousand though, I can see where -- let me back up for a second.

I also see using -- generating this essentially list of lists to me seems to be completely legally defensible. The language in the statute says, develop a process for identification and prioritization of chemicals of concern in consumer products. It doesn't create this kind of bifurcated, first you identify and prioritize chemicals of concern then you do it for products.

I think that may have come out of prior iterations of the draft, that's the way it had been set up, but it certainly doesn't require it in the statute and I think the language that actually mandates DTSC to consider already existing information from other agencies and whatnot certainly supports it. So I think to me it seems that you

have plenty of legal authority to do this.

On the policy end of things to me it seems -- there were some comments about, well how do we sieve down from this. And it looks to me like the way the regulations are set up actually there is a -- beyond just the de minimis sieving, if that's what we call it -- actually in the prioritization of product it looks to me like there's this embedded review of chemicals of concern.

So if you go to page 27 of the regs, seeing as how we all love to read our regs, if you go to page 27 of the regs, the priority product prioritization, in Section 69503.2(a)(1)(A) starts out there with a, with the first element that you have to take into account within (1)(A) talks about potential adverse impacts from chemical of concern and has a series of factors that you ought to consider.

To me that looks like, essentially in the prioritization process, kind of reducing the list of 3,000 down essentially. And the interesting thing is these factors are almost identical if not identical to the factors that DTSC is supposed to look at when they're determining whether to add things to the list.

To me I think what this represents is kind of a more integrated approach to the identification that's kid of linking together further identification and prioritization,

so to speak, of chemicals of concern. And that to me seems to be a perfectly fine way of doing it, almost an inevitable way of doing it, right.

So what this 3,000 then is, is really just a first cut. And it seems like, from a policy standpoint as you've described, that you're kind of balancing having a small enough number that you could tractably handle it, but having a large enough number that you're going to send out those market signals. And perhaps -- and also limit, limit regrettable substitution.

And I guess where I'm coming at now, although I'm like some of the other speakers, which is my views have kind of moved back and forth over the, you now, the last few days and the last few hours, even. But I'm a little concerned that the 3,000 creates some significant problems and doesn't necessarily, won't necessarily achieve the goals for which you've chose that large number.

So for example, let's take the idea that one thing that it would, that it would do is stop or limit somewhat, regrettable substitution, and I think it could have that effect. But on the other hand it might also restrict movement to less-hazardous chemicals of concern.

If I'm looking at this list of 3,000 I'm not sure where things are headed. One might actually, if everything looks roughly the same until the prioritization occurs, you

might decide not to change anything and see how things play out. Because no matter what you change it's going to be a chemical of concern and could end up leading to an alternatives assessment.

So I don't know. I think all we are doing is kind of speculating on what the likely behavioral response to this big number would be but it's not, it's not kind of absolutely clear to me that it would restrict regrettable substitutions.

And let me, let me just -- the point about restricting regrettable substitution is, okay, you've got 3,000. But then, you know, if we take Meg's number of 23,000 I think that leads us with 22,000 -- okay, now you see why I'm a lawyer -- 19,000 --

PANEL MEMBER GUTH: Here, I've got my iPhone.

PANEL MEMBER MALLOY: Twenty, thank you. You've still go about 20,000 chemicals that you could move. So I'm not completely convinced that it gets you where you want to be.

And then the other kind of benefit was that it sends signals, right. I have never been -- I'm a bit skeptical of the kind of market information theories generally but here I think there's a real significant issue, which is, there is such a notion of kind of diluting the signal.

So when you've got 3,000 chemicals it's likely, I think, that, you know, you're going to create a lot of noise in the sense of, you know, it's a little bit like Prop. 65. It's hard to go anywhere and not see a Prop. 65 notice. And what happens when everything is covered by such a notice is it loses its value, right, and people stop responding to it.

So it's not clear to me if this is about -- if many, many, many ingredients used in products are on this very large list that you're really sending any kind of signal other than that we're worried about a lot of things. And so it's not clear to me how that's going to move.

Now okay, so I could be wrong, these could all still be all positive things so would that be kind of enough policy push to say, well keep the 3,000? And I probably would say yeah, why not, right? Because it's not clear to me it does a whole lot of harm and it makes things perhaps more manageable. But that's where I run into some concern.

So I think about the 3,000. I think that makes prioritization much more problematic to have 3,000 chemicals which are then going to take the factors set out later in the regs and try and get down.

For example, in your first cut to three, two, three, five product chemical combinations and you're going to do that without information collection authority. So that to me seems, with 3,000 chemicals, to create maybe that

analysis by paralysis point that Bob Peoples was raising.

And it worries me from a legal standpoint that if you're trying to identify two to five kind of good, first product chemical combinations to go after but you're kind of trying to winnow that out of 3,000, that's an awful lot of justification that you've got to do to show that these particular factors that you've identified in the reg have been applied to 3,000 as opposed to, let's say, a more manageable number.

And I don't know what that number would be, I don't claim to know what that number would be. But the 3,000 really worries me in terms of whether it's actually manageable. And if you're not getting a lot of bang for the buck on the flip side of that in terms of the benefits you're getting on the 3,000 then it would seem to me that that would counsel towards making the number a bit smaller so we can make the prioritization process, which is what we are after here, even more manageable.

CO-CHAIR GEISER: Tim, could I ask you to shorten up a little bit because I've got about eight people and we've only got about ten minutes.

PANEL MEMBER MALLOY: Okay. I should put my card up earlier. But I got yelled at when I put my card up first the last time. You can't win around here.

(Laughter.)

CO-CHAIR CARROLL: There is no winning, Tim.

PANEL MEMBER MALLOY: Yeah, I just have a couple of other short points to make. One is, making the number big also has some down sides later on so there's the authority under response actions that require adoption of an alternative if there is an alternative that doesn't contain a chemical of concern. The larger you make the universe of chemicals of concern the more you shrink that response authority. Even if the chemical of concern is of just marginal concern because you have reached so broadly to pull in your 3,000. I don't know that is actually going to be the case because of the 3,000 but I think that's a concern you ought to have.

The last point that I'll make is that, you know, not to just point out problems. It may be that if what you're concerned about is regrettable substitution dynamics going on there are other ways, I think, than having a very large universe of chemicals of concern that could address that particular factor. I have a couple of examples but in interest of kind of moving things along I won't share them here but I'll talk with you about them separately. Thanks.

CO-CHAIR GEISER: Thank you. What I'm going to do is try to make sure that everyone who hasn't spoken gets a chance to speak and then we'll see how much time we have left. So Joe.

PANEL MEMBER GUTH: Thank you. Well, to get to a shorter list than 3,000 you kind of have to go through the 3,000 anyway, right? These are chemicals that have already been identified by authoritative bodies and I don't know, I don't see how you wouldn't be starting with those in a winnowing process anyway.

But 3,000 is a prioritization. I don't know who said that, somebody said that. You know, because many of those are pollutants anyway. So if we're talking about chemicals in commerce and pollutants how many hundreds of thousands of chemicals, you know, are there out there.

One data point that's interesting about this is the European Union in developing REACH looked at their new chemicals program because they did have some no data no market requirements in that program even before REACH. And they concluded that 70 percent of the chemicals that have gone through their new chemical program had some kind of hazard associated with it.

Now sometimes it was flammability or something like that, it wasn't necessarily toxicity. But that was part of their baseline conclusion that a substantial portion of chemicals in commerce are likely to have some kind of hazard associated with them. And so this is not an idle, you know, exercise at all to start looking at chemicals comprehensively and systematically.

So I think the regrettable -- even with 3,000 chemicals I think that it will help with the regrettable substitution problems to some extent but I just think that, you know, it sounds like a big number but the universe of what we're dealing with is a lot bigger than that so I think there will still be a lot of substitutions. I mean, the easiest way out of these regulations is as soon as that list of 3,000 comes out is to switch out of them. If you switch out of those 3,000 you're done with the regulations for the foreseeable future. And I just -- there's a huge motivation to do that.

So what's the solution to that? I am actually going to offer something. I'll try to make it fast, though. We can do a minimum data set. That's one solution chemical policy reform advocates have proposed and REACH is doing.

Another thing that DTSC tried in some earlier versions of these regulations was to put in a process for as soon as a potential COC was identified that any switching out of that COC after that there would have to be notification and, you know, explanation of what the chemical was switched into. I think the environmentalist community -- it was in response to those concerns about regrettable substitution that that was tried.

It was admittedly very unwieldy and it looked just administratively difficult to actually make it work and so I

am not advocating that DTSC do that although that was the incentive. But I do want to suggest that maybe there's a possibility here for doing something that would be much less administratively burdensome and actually could start to shed a little light on this whole process that we're sort of speculating about.

And what I'm -- what I want to just throw out there and I've only partially thought it out but what if, you know, once the list COCs is identified there were some kind of, you know, minimal, administratively easy process for companies to notify DTSC if they switch out of those chemicals or reformulate to reduce them to say, below a de minimis level. Maybe they don't even have to tell you what they switched out of or into. Just something that was sort of, you know, administratively fairly easy and it could start to create a window on how much this actually happened. Because we don't really know, we're sort of speculating about it.

I think we heard a comment that people have switched out of the Prop. 65 list of chemicals, you know, into safer ones. I'm not so sure. I don't know. I think people are concerned about that. So it might be an opportunity to create a little window into what the consequences are of a list like this. And I just want to suggest that maybe there's a way to do that that would be,

you know, not too difficult or too burdensome.

CO-CHAIR GEISER: Thank you, Joe. Dele.

PANEL MEMBER OGUNSEITAN: Okay, thank you. So this falls under the unforeseen consequences of this approach. I quite like the idea of beginning with lists and I don't see much wrong with the current list. And I -- I have been a little bit concerned about the chemicals for which we don't have information. And this is not to redeem Philippe -- what's his name? Grandjean.

So last Thursday he published a paper in Environmental Health called The Matthew Effect in, in toxicology, essentially. And I just want us to keep this in mind as you look at these lists, especially because they will probably be static for awhile.

And the article was a bibliometric analysis of publications on chemicals of concern. And what he showed was that 20 chemicals dominated publications in the last ten years. Whereas chemicals which some regulatory agency has flagged for lack of information got maybe zero. For example, quaternary ammonium compounds didn't have any publications at all on them.

So I am a little bit concerned about this list suffering from the same effect. I see all kind of contain the same types of chemicals. And those things for which we may have suspicion we will have no information on those

chemicals. And when it's time to do alternative assessments, would simply get replacements and reports that there is a lack of information. There is really no solution to this except to point it out as a potential consequence of coming up with lists that everybody agrees to.

CO-CHAIR GEISER: Thank you. Art.

PANEL MEMBER FONG: Thank you very much. You know, in terms of the size of the list and the number of lists that's included for chemicals of concern identification. I actually, to use some of Debbie's terminology, I don't have the heartburn with this. Because the lists are already out there. Everybody knows what they are. And the major manufacturers -- you know, in fact, refer to these. Major manufacturers refer to these lists when they're making decisions about a product anyway.

I do have some concerns about some of the specific lists that are included on the current list. And the first one is something that George mentioned about, you know, some of these lists are for, you know, ranking purposes. So even chemicals that have actually be designated as safe within that list, unless you specifically specify that those are not included, would --

So a good example is the last one on page 3 of 7 of the Attachment 1, the US EPA Integrated Risk Information System. Nobody can argue that, you know, the EPA IRIS isn't

an authoritative list.

But instead if you're just looking at the chemical carcinogen identification, I'm assuming that you mean that only chemicals in there that have been classified carcinogenic to humans and likely to be carcinogenic to humans would get on this COC list. But instead that list includes, you know, chemicals that have suggested evidence of carcinogenic potential, inadequate information to assess carcinogenic potential, and lastly, not likely to be carcinogenic to humans. So as I get into the COC -- and that's something that George mentioned about another list.

And two other -- given the time, two other lists that I have concerns with are some of the lists related to PBTs. So the state of Washington Department of Ecology and the Canadian Environmental Protection Act persistent, bioaccumulative and toxic chemicals.

I don't know if DTSC has gone into the lists in any depth but included among those chemicals that are on the PBT list are -- the criteria for selection to be on the list includes chemicals in which there are no data. No human or animal data but got on the list because the log octanol water ratio is greater than five.

It's kind of hard for some parts of industry not to have heartburn for inclusion of chemicals in which there is no scientific data. And there is much debate about

relative usefulness of something -- I'm not talking about human structure activities relationship. That's different from just the log octanol water ratio. Thank you very much.

CO-CHAIR GEISER: Thank you. Jae.

PANEL MEMBER CHOI: Okay, let me go through that question here. Are these the right lists? My question is, right -- to me the 3,000 is way too many. The 22 number is, you know, to me is more reasonable.

I think in terms of, I think Odette mentioned this morning that, also I think this session mentioned that legislation can be extended or added, am I right? So I am very, you know, coming from very practical point of view.

I don't know much about toxicology to tell you the truth. I am not an expert. But just giving, you know, three personal examples so you can conclude where I'm coming from. You know, the early 1970s, you know, I was in Bell Labs and we tried to develop the first, the world's first coiled telephone cord. So, you know, I came up calcium zinc complex, you know, to be compounded into PVC.

So here the toxicology in Bell Labs came to me saying, okay, you know that that will kill the rat, you know. So I said, okay, but I don't a rat was going to eat a telephone cord.

(Laughter.)

So I convinced my manager, I think we should do

human test. So, you know, we paid for a clinical, you know, organization in Pennsylvania and they gathered about, you know, 160 people volunteered, and at the end of six months trial nothing happened. So that's number one example.

And the other one is, you know, 1970 we tried to come up, you know, non-lead solder paste system.

So, you know, we -- way before ROHS. So we came up with tin silver copper and tin silver -- you know, we successfully replaced, you know, tin lead solder paste with tin silver copper. And then about five years ago or whatever, copper kills fish. So, you know.

So what I am trying to do is, you know, in terms of coming with up with a rich list or that but I think I -- many of you already know, many of those chemicals have never been tested in a way that human really need to concern. So --

Well, another example. Epichlorohydrin epoxide. Yes, it is carcinogenic, that's proven. However, you cannot use epoxy on printing wire board. Why? Because epoxy is causing cancer. No, that's not true because once, you know, epichlorohydrin or epoxide -- and there is no free epoxide. I don't see any, you know, toxicological effect on human being, for example.

What I'm driving at, I think that DTSC I think did a wonderful job in terms of rationalizing,you know, their

list of 3,000, which I think is too much too. But with respect to what's the next step in terms of this legislation is to me, is really -- I mean, we're talking about authoritative body. I don't know what authoritative body means, really, to tell you the truth. Because so many of the groups, teams, organizations coming up, you know, different lists every day.

My proposal here is, you know, seriously consider the way that DTSC come up their reasons of 3,000 compounds or chemicals and then, you know, start -- as of this morning, I mean, you know, immediate implementation. And then, you know, the toxicology to me, it is going to be continuously evolved as the real, you know, human cancer tests or whatever, you know. So that at that time we can add additional information.

That's what I think we needed to address, to me. How we can continuously expand the list to make sure that we are not really jeopardizing all, you know, consumer product industry. But yet we have to have a very good regulations so that, you know, it will not have any, you know, health impact on, you know, human beings.

CO-CHAIR GEISER: Thank you, Jae. So I have Roger. And then I'm going to -- go ahead, Roger. I think just in respect to the fact that George won't be here tomorrow I will ask you to stay on and we'll have a short

comment from you. But next, Roger.

PANEL MEMBER McFADDEN: This is my first opportunity to speak today and I'd like to join my colleagues in congratulating you on an excellent summary and also a strategy.

But let me, let me begin by saying that I am so thankful as a participant in my business that I don't have to take a policy that I draft and have to run it by this group.

(Laughter.)

CO-CHAIR GEISER: We're open, Roger, we're open to try it.

PANEL MEMBER McFADDEN: I was thinking that if one of our products pops up on this list and there was a chemical in that product that was on a COC list that was published, so how would we handle that as a business? My bet is that if we look for an alternative we're probably going to want to make sure the alternative isn't going to show up on one of these lists.

Now whether or not you put that list here or not, nevertheless my bet is that every company that's around this table and out there listening is going to probably say, you don't want to invest in an alternative here unless we're pretty darn sure that we're not going to have to face this again.

So I think in a way this list discussion is important but it's not the most important thing. The most important thing to me is the outcome. The outcome is safer chemicals. That's what we all want. We all want that. And I think that this is going to do that. Whether you pick three products or four products or ten, the fact is companies are going to pay attention to this and they're going to take action.

You see, on that list of chemicals, there's somebody that loves every chemical on that list. There's somebody that loves every list that's there, if they generated it and they made money from it. So I think we have to be practical here as much as we want to make sure this is right. We still have a practical world we live in. And the practicality is that we're probably going to face the fact that we're going to look at these lists either you publish them or we're going to fine them. Let me look at my notes.

Oh, what's missing? The list of preferred chemicals. That's what's missing. Now you can't generate those. But if I were looking for a, you know, if I were researching I'd want to find where is my list of preferred chemicals. My hope is that somewhere in this process here after you go through all these AAs and everything there's going to be generated a list of preferred chemicals.

Because that to me is the bottom line here. It's the outcome. We spend too much, so much time talking about the problem. We've been spending three years talking about the problem. We know what the problem is. The problem is we have some products out there today that have some chemicals in them that we wish weren't there. Now whether or not we wish they weren't there, consumers are driving us towards finding alternatives and I think we owe them an answer.

So whether this is done in California or it's done in the state of Washington, it's done back in Washington DC or it's done in a very large company, it makes no difference. The reality is we're going to be facing that. And I think that this, what you've drafted here -- and certainly it needs work. Certainly there's things here that my colleagues have brought up today that need to, you know, need to be factored into this.

But at the end of the day I think you've got something here that's very meaningful and practical. Now legally defensible, I'll leave that up to Tim and some of the legal people to decide those kinds of things, Colleen, on legally defensible. But I think it's practical and meaningful from our point of view. Thank you.

CO-CHAIR GEISER: Thank you. So George, if you could be brief, though.

PANEL MEMBER DASTON: So three things and I'll make them really brief. First of all, you know, to agree with Meg about the specific NTP CERHR or OHAT list. I think we're exactly in the same place. But the reason that I bring it up again is pretty much the point that Art brought up, which is, you have to understand how these lists are created.

And in the case of these particular lists there is a very thorough process that ends up with a group of experts, very transparently after reviewing all of the information in the literature with five categorizations of concern, two or three of which would probably not make any list. So if there is a negligible or minimal concern.

There is also a second process that' done by the NTP staff which is not transparent, which is not public, where they create their own list of hazards. I would argue that would not be an authoritative list because of its circumstances. And it's just an illustration of how you need to know how something gets onto a particular list. So there is more of an art to this than meets the eye.

And I think that, you know, if you do want these lists to really truly be chemicals of concern, you know, you're going to have to really evaluate them. And my continuing recommendation is to pare down the list of things that are very authoritative.

The second point is, it's a detail but it's around the de minimis levels. And I don't want to argue about the .1 or .01 percent. You've made a policy decision with transparent reasons, that's fine. The concern -- and also you have the leeway to go higher or lower, which is great. I mean, I think that that's basically the wonderful navigation of the input you got.

The problem that I have is that you do it for nine end points, only six of which have any sort of regulatory definition, three of which don't, immunotoxin, neurotoxin, endocrine disruption. Endocrine disruption is a mechanism that will cause some of the other effects, that's not an issue. But it's going to be a concern so you're going to have to either define that or figure out a way to define what's an immunotoxicant, want's a neurotoxicant in the case of the de minimis. So just something for you to do.

The third thing is, I was actually really delighted to see the phrase about cumulative assessment of things that cause the same hazard traits and have the same mode of action. I think that that's important to have the "and" there. And this is where I disagree with Meg. Clearly the impetus for that was the NRC phthalates report that suggested that we should just be doing things on end point but they were very vague on how they defined the breadth of an end point.

And so, you know, the phthalates example is where two different modes of action both come together in the same toxicity pathway, i.e., decreased androgen signaling during development and cause adverse male reproductive toxicity. They are not talking about just anything that causes developmental toxicity, anything that causes neurotoxicity. And that's really the broad level of end points that's been talked about in these drafts.

So if you don't clarify that as being the same hazard trait and the same mode of action, I think it's mode of action that probably needs better defining, then I think you're going to end up asking people to add up a lot of things that from a scientific standpoint ought not to be added. So those are my brief comments.

PANEL MEMBER SCHWARZMAN: Can I make a quick --

CO-CHAIR GEISER: I am trying to wrap this up and we are well over at the moment. Rich has asked for one 60 second comment.

PANEL MEMBER LIROFF: Twenty seconds. Just very quickly on Roger's point about how companies will respond, where they want to go. Roger said, you know, we want preferable chemistries. Just go on to the web, look at Nike, look at their restricted substances list. Look at the recent provisions which talk about the 12 principles of green chemistry. And they're creating competition among

their suppliers to give them chemistries which satisfy those criteria or approach those criteria. So this is the mechanism that we're talking about, it's that moving ourselves away from the existing group of chemistries we have, towards greener chemicals.

CO-CHAIR GEISER: Thank you, Rich. All right, I think I'm going to wrap this up. Please remember that we're going to have some time tomorrow at the end of the morning where we'll have a general session again if you're still holding on to some important statements. And I know several of you kindly put your cards down. Please hold on to those ideas.

I think what we're going to do is take a break and then we'll come back and pick up George's one comment before we start into the rest of this. So thank you.

CO-CHAIR CARROLL: And let's do the following. Let's break until 3:30. I have the next session. We technically have until five o'clock. I'm not going to take ten minutes to summarize the day's discussion if it's not necessary so I think we can have until 3:30 and still go to five.

(Off the record at 3:16 p.m.)

(On the record at 3:30 p.m.)

CO-CHAIR CARROLL: I hope you'll forgive me, I had to go downstairs. We have come to Question 2 for the

afternoon, which you have on your handout, which is prioritization of products. I suppose you could read the question but I'll read it to you anyway. Yes, I see a hand in the back. Go ahead, Meg.

PANEL MEMBER SCHWARZMAN: Just regarding this issue of mode of action when looking at cumulative impacts and do we strike mode of action or do we keep it. Just, we can go over it in detail with Odette and Debbie. But George and I talked at the break and realized that we have actually agreed. And it's a wording issue and we'll get back to you offline about it.

CHIEF DEPUTY DIRECTOR MADRIAGO: Okay, thank you.

CO-CHAIR CARROLL: Very good, thank you. So:

"The decision was made to use a narrative standard for prioritizing products and selecting those products that will be placed on the Priority Products list. The narrative standard includes consideration of: (i) potential adverse impacts from the COC(s) in the product; (ii) potential exposures; (iii) availability of reliable information to substantiate potential adverse impacts and exposures; (iv) protections already provided by other regulatory programs; and (v) the existence of available viable safer

alternatives."

So the question for discussion at this point is:

"What steps might be included to structure the prioritization process so that manufacturers are better able to predict the likelihood of their products being listed as Priority Products."

And I'll open the discussion there. Dale, you have your card up.

PANEL MEMBER JOHNSON: Yeah. Part of this also is a clarification question in that for a manufacturer, and this gets into the prioritization thing and the manufacture. So when the manufacturer sees the chemical of concern list and then has a product sitting there, when does the manufacturer have to notify the Agency?

CHIEF DEPUTY DIRECTOR MADRIAGO: Okay, I'll answer that very quickly. There is no requirement for notification until we actually listed a product chemical combination on the priority products list. That's what triggers the notification requirement.

PANEL MEMBER JOHNSON: Okay, all right. Then moving on from there. I think probably the biggest issue in this area that I see is actually taking the information from the various lists and from hazard traits and everything else and actually getting that to a point here you could actually

say that this is, now falls into a priority.

And I think that the difficulty for me on looking at that, and as I have discussed with other people, is to take the broad hazard trait list, the OEHHA broad list, and then put that into context as it relates to whatever it is for that particular product or whatever. That's a pretty detailed, analytical process and so I think that's going to be an area that's going to be quite difficult, I think.

Now when it becomes less difficult, I think, if there are these priority categories. And it appears that you could look at this, you read it very carefully and there are priority categories. And those priority categories then define exactly how you're going to do this.

And that's kind of what I read into it is if you look at the way the thing is set up you already know how you're going to prioritize things in terms of the chemicals. And therefore you're going to get down to the products and the products are going to relate to use and you're going to eventually get down to the teething ring, as an example.

So I think, so I think it's set up in there, you know. It doesn't say it directly but it's set up how you're going to get there. Am I, am I correct on that? Is that kind of the concept of what's --

CHIEF DEPUTY DIRECTOR MADRIAGO: I want to say this very quickly. One of the things we heard last time

around was that you couldn't bifurcate the chemical prioritization and the product prioritization process. So what we tried to do in here, and maybe it wasn't clear enough, is that chemical identification kind of sitting out here by itself. But for real prioritization you need to look at the chemical product combination together.

So you're right and Tim kind of alluded to this earlier. That embodied in that product prioritization is prioritizing the chemical.

CO-CHAIR CARROLL: Thank you, Dale. Kelly.

PANEL MEMBER MORAN: I just have a couple of thoughts here. The smaller but important thought is that I know that the process here is intending to capture costs in the prioritization, the costs to say local governments or businesses or individuals who purchase a product and then have to deal with the cost of disposing it. Or local governments have to deal with hazardous waste disposal or problems with their sewage treatment plants or urban runoff programs.

It's pretty hard to find those costs in there and so I'm going to be thinking about wording on that and how that fits in. And that affects the prioritization scheme of both the sort of overall narrative criteria as well as the key prioritization criteria. I'm a little worried that that hasn't correctly captured -- that's a really important

balancing factor for the state since it's saving the state itself as well as California municipalities money. That's going to be a big factor coming up.

But you had asked us specifically, the question you're really looking for input from us then is how do we make this more predictable in light of a narrative standard? So that's where -- I have other comments but I think that's the one you really want to talk about.

And first I want to preface it by saying I think I agree with the Department's conclusions that a narrative standard is the only thing that is really going to be robust enough to survive the test of time here and so it seems that it's an essential approach from the scientific and management perspective. But that does create of, well how do we know if it's there.

And I have been thinking about that because I actually think that what is here is a little too specific in ways and it might tie the Department's hands. And we had earlier mention of a couple of phrases here that might be problematic and I was also getting kind of stuck on those. That these might be so narrow in the way they're written that if the chemical interferes with the operation of a sewage treatment plant's processes then the chemical that isn't the thing that's important that comes out the other end, you wouldn't be able to capture it as a priority here.

And I don't think you really want that so I'm going to think about wording for that. But that's what I mean about maybe it's already a little too specific.

So another way of dealing with that would be to create predictability in the process by looking out a few years. So the ARB has done that. And many other agencies, they do that. They lay out, here is our plan for not just this round but here is what we're thinking about over the next five, eight years. Here are the things that are floating to the top.

So that gives a different kind of predictability that is still one that is really important for making management decisions if you're a business if you can look out and say, okay, my product chemical combination isn't right now. But I can see that it's on the list and in the coming decade we're going to need to be working with DTSC on that. That's a way of getting that predictability without crating a framework that so ties the Department's hands that it can't tackle a multitude of problems.

And it's going to need to be able to tackle both big and small problems as it moves forward. Because some small problems are very cost-effectively and quickly dealt with by the Department and so I do foresee a mix of things there. So you want to be able to do that mix. And by creating predictability using different strategy I think

you could also meet the needs of businesses and other stakeholders who are looking at that.

CO-CHAIR CARROLL: Thank you, Kelly. Dele and then Bruce.

PANEL MEMBER OGUNSEITAN: Thank you. A brief -- I was not sure why the number five criterion is there, the existence of available, viable safer alternatives. I guess the word before that is "and." So if all of the first four criteria re met there also has to be, for a product to be on the priority list, a safer alternative. And I guess that's a question why the company -- manufacturer would not have explored why they wouldn't use the safer alternative.

I think if the risk is so great and there are no safe alternatives the priority should be on the risk, rather than the availability of a viable alternative. Loaded with that is also what "viable" means. Is it cost-related? Just clarification at this point but we can talk about it more.

CHIEF DEPUTY DIRECTOR MADRIAGO: Okay, so really quickly. Yes, let me clarify that a product can definitely get on the list without there being an existing, safer alternative. We'll take a look to see if we need to clarify the language but the intent is that that is the factor that the Department has the discretion to take into consideration in identifying priority products but it is not an essential criteria.

And in terms of what's meant by, you know, viable alternative, that it's technologically and economically feasible. And I believe there are some definitions in the regulations that get to that.

PANEL MEMBER OGUNSEITAN: Thanks.

CO-CHAIR CARROLL: Bruce.

PANEL MEMBER CORDS: In looking at page 6 of 7 on the key prioritization criteria. And it seems to me that -- I'm not sure --

CO-CHAIR CARROLL: Bruce, I need you to speak into the mic, please.

PANEL MEMBER CORDS: If all those are weighted equally, but it appear to me like (2) and (3) would have more impact. But one of the things I'm concerned about is, if you use say number two, "The product is widely distributed in commerce nd widely used by consumers." But then it ends up like what George mentioned, that it's a minor -- let's say it's a potential carcinogen, not a proven carcinogen. So now you're kind of digging in the wrong place as opposed to something that's a proven carcinogen being used by, let's say, fewer people.

What I try to do -- I've worked for 30 years reducing everything to a nine box grid. So if you say, for example, that the chemicals of concern, you rank them 1, 3, 5 in terms of the potency or the concern. Like a heavy-duty

carcinogen would be a five. And then population exposure down here. If it's less than 1,000 people and it's a five, those people are going to have to wait until round two. If it's an exposure of greater than 10,000 people and it's a major carcinogen, you've got to look at it right away. And, you know, I don't know that these numbers are right but basically anything that ends up on this part of the grid would seem to me to be under consideration for the first handful of products.

CO-CHAIR CARROLL: Thank you, Bruce. Mike. Michael.

PANEL MEMBER KIRSCHNER: Thanks. Just a clarifying question, I guess, and a comment. I don't really understand, and I see this in both the reg and this little handout, why there's a priority product prioritization and then a key prioritization criteria. They seem redundant or at least difficult for me in my meager brain here to try to comprehend. At least, you know -- it's not clear -- what I'm saying is it's not clear to me. If I'm a manufacturer what am I supposed to look at and why to figure what the process is?

CHIEF DEPUTY DIRECTOR MADRIAGO: We'll note that's unclear but let me respond very quickly in case it helps anybody. I guess this was our way of actually giving greater importance to certain factors, those that we have

listed as key prioritization criteria. And so the basic approach is we'll look at, you know, the other prioritizing criteria that are listed first as well as availability of information and other regulatory programs to come up with, you know, a preliminary thinking. And then go back at the end and make sure that what we have chosen, that it's taking into consideration these key prioritization criteria. So, you know, maybe you think that's to complicated and we should forgo it but that was the thinking.

PANEL MEMBER KIRSCHNER: I think maybe some sort of analysis would be -- I don't know if you can make that analysis process a little clearer than having these two sections that seem to overlap, in there.

One point I did want to reiterate actually. Somebody, it wasn't me, somebody brought it up last week in San Diego and I just wanted to reiterate it as long as I have the mic here. And it's in the key prioritization criteria section for assembled products. It just right now covers inhalation or dermal contact. It should also include oral because my kids put remote in their mouth when they were little kids.

(Laughter.)

Articles can get, assembled products can get oral, exposure through oral means. Thanks.

CO-CHAIR CARROLL: Thank you, Michael. I have

Richard, Roger, Tim and Joe.

PANEL MEMBER LIROFF: On the subject of the availability of safer alternatives. There's an argument to be made, I'm not sure how strongly I would want to make it, that the obvious availability of safer alternatives ought to lead to over-weighting of a particular product. Take the case of phthalates. Phthalates have gotten a lot of attention. Some phthalates are more toxic than others.

We know from the manufacturing data that the manufacture of non-phthalate alternatives is growing by leaps and bounds. So clearly there is market uptake of non-phthalate alternatives. So arguably one could get some quick wings from this program. We don't know why some people adopt the alternatives, others don't. But if there are a lot of them doing it already it's simply a matter of sort of hitting somebody upside the head and saying, hey, you know, this is out there. You get some quick wings.

CO-CHAIR CARROLL: Thank you, Richard. Roger.

PANEL MEMBER McFADDEN: Real quick. I would absolutely ditto that last comment because I think safer alternatives is where we're headed and I think if they're available that would be a good place to start spending some time.

The other is, Michael, you were right on. I actually made some notes on that particular section four

because I know my granddaughter chews on -- you know, you mentioned teething. That's in the mouth. Well you didn't, that's right. But I mean, that's in the mouth of the babe. And I think to include oral in that makes every sense in the world.

CO-CHAIR CARROLL: So now we have children chewing on remotes, we have rats chewing on telephone cords. This has been an odd afternoon.

PANEL MEMBER KIRSCHNER: We don't have children chewing on rats yet.

(Laughter.)

CO-CHAIR CARROLL: Good, that's good. Okay, Tim, do it if you can.

PANEL MEMBER MALLOY: Thank you. I had just a few comments. I want to just ask the question, why is the question framed of how we might structure this so as to make it better able to predict the likelihood of products being listed as priority products. Because it strikes me that the more certain you are that your product is going to be listed the less likely everybody is that the program is going to push them to do something in advance of the formal process.

It seems like, you know, the converse might -- you might say, some uncertainty is a good thing if you're a real believer and the motion of the market and so and so forth. And I'll leave that kind of out there just in that point.

But taking the question as it has been asked. You know, my feeling about this is that, you know, we had this conversation before about narrative versus some kind of formal decision modeling and so on and so forth and we all know where that ended.

And having gone with the narrative approach, which I think is a perfectly reasonable way to do things and it's the way many of these things are done, is kind of like the lack of predictability, uncertainty is kind of an occupational hazard of narrative standards. That these are -- the reason it's a narrative standard is because the agency wanted to retain discretion and the ability to be flexible and so on and so forth.

So not only is it not clear to me that making this kind of decision clearly predictable necessarily, you know, is a given, as kind of a design principle, but also I think the more you want to have a narrative approach the less likely you are able to make it predictable.

Now having said that, I do have some suggestions about how to make it a little bit more predictable. And one of them is using some default rules of thumb that could be either put in the regulations or perhaps in guidance documents. Things that are -- we might -- I know Procter & Gamble likes to talk about the show stoppers, right? So kind of a similar concept that there are probably certain

paradigmatic kind of examples of, you know, product chemical combinations that one would say, if we reached a conclusion that this has both a very high level of concern and hazard and children are likely to put it into their mouth, this is a high-level prioritization. So you create a more discrete or more explicit rules of thumb.

I think that's what C-5 was doing but not in a very kind of aggressive way, it was more of a, we're going to give you a little bump or a nudge or something if you fall into one of these. So one way to make it much more predictable would be to categorize it just a bit more to maybe create these rules of thumb.

The other way I think would be to maybe provide some more clear qualitative weighting of the particular factors. And I don't pretend to know what that weighting ought to be but it may be that you could identify that certain types of hazards are going to be, are more likely to move you off the prioritization than others are. So those are kind of examples, kind of structurally, of things that you could do.

And then the last point I'd just like to throw in is Ken made the point earlier that other prioritization factors might include wanting to pick product chemical combinations that are kind of like sentinel combinations. Ones that have a transferability to them that would lead to

more attention or movement in other areas.

And that got me to thinking that this notion of moving from the 3,000 down to 3 or 5, it struck me that there's probably factors that perhaps you have in mind as to what would make for a good first set or maybe first two or three sets of product chemical combinations to address. And it's not clear to me, those are reflected in these kind of general and I think very reasonable prioritization factors to be considered.

To me I think it might be a good idea maybe to expressly identify kind of like first tier or early prioritization efforts and explicitly, like Ken had suggested, identify "and here are some other things we're going to be taking into account here."

One thing I think that does is it does add some predictability. The other thing I think it does is it makes it more legally defensible. It makes me feel a little bit better about, gosh, if you've got 3,000 or 1,000 or even 200 chemicals and you want to get down to 3 to 5 and you want to get down to a certain kind of 3 or 5, if you've got that kind of more explicitly laid out not only is that good for everybody to know up front and you can have a conversation and there's transparency. But I think it's also more legally defensible if something is going to be, you think, driving your decision. It ought to be out front in here so

that you can actually use it without having to kind of fit it in among a more generic set of priority factors. Thank you.

CO-CHAIR CARROLL: Thank you, Tim. I have Joe and then Mike Wilson.

PANEL MEMBER GUTH: Thank you, Chair. I want to make two, two comments. One is on the mode of action issue. I think the point I want to make about it is somewhat different than the one that was being discussed earlier. And that is that I think the EPA has been trying to use that in some of their risk assessment strategies and it is a morass of complexity. Whether chemicals operate in the same mode of action, what does it mean. And if you get finally analytical enough about it -- I mean, there's a lot of fine points you could make about a mode of action.

And if you think about the way it would work in this regulation, it's something that I think the companies that are getting into the alternatives assessment process, they'll be the ones arguing that there are many different modes of action for each of the COCs. And so -- because that gives them more de minimis room for each individual chemical. So DTSC is going to have to be willing to take on that fight, right? And so I think it's just a morass of struggle that is being invited to have that.

So what I would do or recommend is just getting

rid of it altogether. And if you think about why it's in there, especially for the de minimis. I take it DTSC is trying to sort of split the baby on -- you know, on the one side some advocates said, well, all COCs together should total the de minimis, right? And others say, well each one should independently be able to be at a de minimis level.

And so you're kind of splitting the baby by saying, well, okay, ones that are similar, those have to be added up. So you could just say, all the carcinogens have to be added up. I mean, it's kind of a policy decision where you're splitting the baby. The particulars of the mode of action, I mean, it doesn't really matter, you know. Because what you are trying to accomplish is something different than EPA in doing their risk assessment. So I just think that it's not going to be worth the intensity of analytical struggle over it that's being invited.

All right, now the other point I wanted to make is on -- in many places in the regulation there is an articulation of the degree to which a chemical is likely to cause adverse impacts. We're talking about how certain is it going to have to be that the chemical is a cause of adverse impacts for it to be either identified as adverse? Public health impact? That's in the definition of adverse, public health impact. And then as a criteria for whether it's a COC, whether it's a priority product. It's coming up

in all these places.

And I think the language that's being used is setting a pretty high burden for DTSC and I don't, I don't think it's appropriate in these circumstances. For example, for a COC, potential for a chemical to cause adverse effects. I mean, usually if you're thinking about a more precautionary approach or an approach that, you know, takes account of uncertainty in the data you would talk about "may cause" or "potential threat" or something that doesn't require quite -- I think this can be read to require quite a strong degree of confidence that the threat is being caused.

And I don't think that's what you want in the context of being a factor that you're looking at as part of a prioritization process. So I would really suggest going to some other type language.

And then the same thing I think in the regulatory response. There's a whole different phrase, I'm not sure what it means. "Does not pose significant potential adverse public health impacts." "Does not pose." I mean, I'm not sure what that means, that's a little awkward. So I think that language probably should be conformed and I think moved more in the direction of "may present a threat."

CO-CHAIR CARROLL: Thank you, Joe. I have Mike Wilson, Meg and Ken.

PANEL MEMBER WILSON: My concerns I think echo

those that Joe just described around the priority products prioritization. That's within our purview of this discussion, is that right? Good. I was getting a little lost.

One of the things that concerned me about the language was the scope of things that DTSC is required to consider. Does that mean that -- first of all I guess it's a clarifying question. One is the potential adverse impacts from chemicals of concern. DTSC is -- It states here that you are supposed to consider A through F. And then you're also required, it sounds like, to consider a set of exposure metrics of various kinds. Does that mean that the Department is required to consider each of these aspects, each of these points before making any sort of decision?

PANEL MEMBER SCHOENUNG: What page are you on?

PANEL MEMBER WILSON: I'm sorry, I'm on, I'm actually looking at Attachment 2 under the Questions for Discussion handout, which is the Priority Products Prioritization.

CHIEF DEPUTY DIRECTOR MADRIAGO: Well, I believe our concept was that we would be required to consider these to the extent information is available. I believe someplace in here is that. I'll have to look.

PANEL MEMBER WILSON: It says "shall consider both of the following."

CHIEF DEPUTY DIRECTOR MADRIAGO: Right.

PANEL MEMBER WILSON: So if I imagine myself in your position, potentially receiving information on perhaps a few thousand products from companies reporting to you that their products contain chemicals of concern, then I imagine, you know, sort of sitting down with that information and trying to, trying to come up with some sort of decision based on what appears to me to be a very high level of understanding on potential adverse impacts. It seems like a very high bar that -- this seems to me to be a choke point.

And, you know, it also, it doesn't seem to me to be, to be necessary in that it may be simpler, and if we're getting to this question of, you know, how do we signal to companies that their product may be captured by this regulation? Well how do we do that? Well one might be that those products that contain the highest proportions of chemicals of concern that we have identified in this first step -- and perhaps as other speakers have said, the nature of those chemicals.

It may be that we need to prioritize within that chemical of concern list without having to take on a further level of analysis. So without having to go into aggregate effects, cumulative effects, similar modes of action, all those different kinds of things. Making a much more simple determination of the presence of chemicals of concern and

the nature of those chemicals as the first screen on the hazard side.

And my instinct would then be to go immediately to the exposure side and to -- and again, I think what appears to be a requirement of the Department to consider a long list of exposure metrics of different kinds seems to me to be a high bar again. That there may be more, there may be simpler metrics of exposure. And they may be contained within this but this in itself is a lot of information to assimilate and work with if you're trying to move briskly through the process.

So it seems to me that the prioritization process should be a fairly simple hazard characterization based on the chemicals of concern identified followed by a fairly simple exposure matrix. And then the special considerations piece. Those products for which children, pregnant women and other sensitive sub-populations may be exposed, environmentally sensitive habitats. And you have a somewhat catchall widespread public health or environmental impacts giving sort of a final screen to, you know, raise to the top the chemicals, the products that are going to be relevant to those populations. Sort of in that sort of three-step way.

And just a very small point. The widespread adverse public health and/or environmental impacts. Public health wasn't defined in the, in the set of definitions and

so it wasn't clear to me if that, if those, you know, does that include occupational settings and so forth. So that might actually be helpful.

So I'm calling I guess in general for the point of steadily moving chemicals of concern out of commerce and streamlining, simplifying this process and reducing the burden on DTSC before you're able to take action.

CO-CHAIR CARROLL: Thank you, Michael. Director, we have Megan, Ken, George, Julie and Dale in that order.

DIRECTOR RAPHAEL: And you. Everyone is taken care of.

PANEL MEMBER SCHWARZMAN: Thanks. I might have read this a little bit differently but maybe there's a quick language change that kind of bridges between what Mike was just saying and what I'm thinking. Which is around this issue of, is this list too exhaustive. And I think when I was reading the regulations I interpreted it perhaps incorrectly as, these are all factors and criteria that DTSC can take into account.

And so maybe there is some language clarification to make because I applauded these factors, actually. Oh good, you don't have to consider a chemical in this one product in isolation. This allows DTSC to say, well, this isn't the only source of this chemical. Or, this isn't the only chemical that has this effect in this product. And so

it was giving DTSC some room to move in a way that is much more scientifically defensible than a more straightforward, this one chemical in this one product and is that impact significant enough to warrant action.

So my guess is that's your goal also, Mike, and so maybe whatever language it was that's here that made that seem burdensome rather than permissive, you know, staff can -- or we can work with staff to help figure out wording that accomplishes that.

Since this language shows up in the prioritization also I now get to take this opportunity to clarify and celebrate this agreement among panelists over this issue of mode of action. And part of it I think is I wasn't clear the first time I brought it up. So the US EPA definition of mode of action I think will be helpful here, which is the sequence of events starting with the interaction of an agent and a cell. So something, an agent, an external agent, comes in contact with a cell and there's a whole cascade of events. And that leads to functional changes that lead to disease. So when US EPA defines mode of action of a carcinogen, it's the sequence of events that follows the engagement of a chemical and a cell or something like that. A chemical in DNA or whatever, and that leads to disease.

So I think what we are all saying is that's too fine grain a level of detail, to require that chemicals have

that exact same cascade of events. But what we are asking for is specificity, like I think what George was saying. The bottom line there is specificity about the outcome. So not to say anything that's a carcinogen, maybe those aren't appropriately grouped. Or anything that's a developmental toxicant, that's too broad a group.

So I turned back to the OEHHA hazard traits regulation and there's a difference, a language distinguishment that I think is helpful there. So they use hazard trait to talk in more general terms like carcinogenicity. And then they say toxicological end point for that hazard trait. So it may be that we strike mode of action and instead replace it with "have similar toxicological end points." And that that would address the need for specificity without getting into what receptor does this chemical interact with and which kind of cell. So I think that's all I had to say about that point.

The other issue is one I raised earlier and I think Ken has a relatively easy solution also. And that's this issue of DTSC is allowing itself to consider aggregate exposures. I'm assuming we're striking "effects" and replacing it with "exposures." That that doesn't really square with the requirement that something have significant potential exposure in a quantity that can result in that adverse effect.

My read of all of the different exposure criteria that are in here is that there are sufficient ways of gathering exposure information but you can simply strike this issue about exposure in quantities that result in adverse effect. Because there are already things in there like widespread production and biomonitoring data and lots and lots of other good ways and creative ways that you folks up for thinking about surrogates of exposure and things like that, that you can just lean on instead.

CO-CHAIR CARROLL: Thank you, Meg. Ken.

CO-CHAIR GEISER: So let me just expand a little bit on what I said right before lunch. You know, the Department has, in my mind, two levels of decision-making here that are about selecting things. One is what's on the list and two is what's a priority product. What's on the list we have already discussed for an hour and a half.

But the thing about it is, if you're substance is on the list it's no big deal because -- well, that's wrong to say. But it's not as big a deal because you don't, it doesn't cost you a lot if you are a producer in California or something like that. You may be unhappy that your substance is on a list but it's a little hard to go after that question because it's already on somebody's list or it wouldn't be on that list so it's hard to challenge there is some odd reason why your chemical shouldn't be on that list.

So it seems to me, you're not going to get a lot. The Department is not going to get a lot of trouble over that.

On the other hand, selecting a product is, first of all it's going to cost somebody a lot of money. And not only that, it's going to cost some potentially market share and other such things. And this is a narrative process so it's open to challenge. Therefore it's really quite -- I guess what has happened to me is I'm so pleased with this set of regulations that I'm just assuming this is it so my mind has now lunged forward to, now how are we actually going to implement this thing. So I'm thinking of myself as an administrator of this program trying to think about, okay, how would I cleverly use this next step.

So what I'm thinking is, okay, so how would I choose the substances, the products that would A, be defensible so I'm not getting a lot of court challenges. But at the same time we do what I was suggesting earlier, kind of leverage big market changes such as -- because I can only -- it's sort of -- Jeff used the military metaphor awhile ago, I think I would be using that a bit too. I have a small arsenal. I've got a huge, wide array of things that I'm trying to do with this. How can I leverage the products in the most clever way that actually moves the market? I can only move one product but I've got a whole market I've got to move.

So it seems to me I would first of all take some very, some very specific things like maybe select products for each of the three -- one has to do with children or pregnant women, one has to do with environmentally sensitive habitats and one has to do with the widespread, adverse public health.

I would also when I announced the products I wouldn't just drop, I wouldn't just open a window and throw out the names of them. I think I would basically throw it out in a little statement that said why I selected these. And the why would be hinting at how others could have been selected in that same category such that, aha, they selected this product. But what this product really is, is a sentinel product of a larger class of products that we are actually interested in.

So for instance I might do DEHP in children -- infants' play toys or something like that. And I might select that because -- well first of all there's a wide number of alternatives.

Second of all, phthalates show up in lots of children's toys. So I would be picking a wide array of possible, a sector where there's a wide array, but I'd be selecting one. But I'd be selecting one where there's a lot of alternatives. So I'd be getting a lot of bang for a quick buck out of the thing.

I would also think just for learning that I might select a product where there are not any alternatives as well. Just to try to see if you can push alternatives in an area that we might be tough. I might choose something like formaldehyde in, oh I don't know, in nail polish or something like that. Where again, the impact could be large because it might have a lot to do with consumer products. nd I might say, I'm interested in formaldehyde in consumer products. I'm selecting this one because I want to really look at it very intensely. But there aren't a lot of alternatives so I may try to push out -- I'd be a little technology-pushing as well.

So I think I would be very strategic. I would basically come out with a plan that says why I'm choosing things, hinting t what we might do the future, et cetera.

So then I go back to the regulations, see. Would that make me change the wording of these regulations in any way? And you know what I was thinking? No. I actually think the regulations fit as a platform that allows for a lot of flexibility in doing that kind of thing. So I don't really have a suggestion for the, for the regulations but I have a lot of suggestions for what you should do next.

CO-CHAIR CARROLL: Thank you, Ken. I have George, Julie and Dale.

PANEL MEMBER DASTON: Thanks. First of all, since

Meg and I have this ping pong game going. You know, the only alternative that I might suggest is that we, instead of dropping "mode of action" just make sure that we have it pretty rigorously defined. The reason I say that is virtually everything that I'm good at people having been calling a morass and a quagmire all day and I'm starting to get sensitive about it.

(Laughter.)

So that's not really why I put my card up. You know, I guess when I was starting to think about this question around the product selection thing. You know, one thing that struck me that I had no answer for was the -- what might be an apparent randomness that might come with the selection of two to five products to start with. You almost have to be fatalistic. It's like, you know, the bullet might come and it might not.

So that said -- and I had lots of stuff that I had prepared and Ken basically I think said it all. And so the only thing that I might add is, you know, there's a real power to this narrative approach whereby I think that if you did go through fairly rigorously this list of criteria that you crafted for product prioritization, if you pretty rigorously went through those in the first set of products that you decide to pick, I think that that will have a lot of value in terms of setting precedent and allowing people

to understand, you know, what sorts of criteria, you know, you think are most important.

I actually think these are very good, you know what I mean. I think the whole purpose is to make an impact in terms of public and environmental health. And I think that, you know, you can do that by choosing the right products but also making really transparent in the narrative statement how you think that's going to make a difference.

CO-CHAIR CARROLL: Very good, thank you, George. Julie.

PANEL MEMBER SCHOENUNG: Thank you. Well my original thought was prompted by Mike's concern about the distinction between the product prioritization and the key factors for prioritization. But it also evolves now with Ken and George's and other comments. And that is, I'm a very visual person. So unlike Tim maybe who can digest all the words, I digest them better once I've tried to put them in a diagram.

So what came to my mind was to try to articulate sort of a decision flow diagram that could be used either formally as guidance but then you lose your narrative flexibility.

Then I was listening to how do you implement it and what are the ramifications of this in terms of really being able to implement it, just as an exercise of creating

a decision flow diagram that you think matches what this text articulates to see if you can actually get to the products you want.

Writing a decision flow diagram I'll agree is not a simple thing to do. With another group I'm involved in we have been trying to write one that's only about six boxes long and we can't get all ten people to agree on how to articulate it. But if you can get a diagram that sort of says, okay, when is it yes and when does it go here and when is it maybe, when is it no and then go to the next factor that you consider.

And work your way through this process that you articulated and see whether or not it works. To give you the priority products that you're already anticipating would probably trickle to the top. And then that would also help identify whether or not your language needs to be modified. I don't know whether it makes sense to put it in guidance documents, I think that might be too constraining. That's my thought.

CO-CHAIR CARROLL: Thank you, Julie. All right, let's just check to see where we are. I have Dale next and I'm going to honor that because your first intervention was really more in the nature of a question than a statement. Then I have Art, Dele and Ann. Now, before I come back to you, Kelly, I want to check to see, Julia, Jae and Bob, if

you are interested in an intervention here in the first round? Because everyone else will have spoken.

PANEL MEMBER QUINT: No.

PANEL MEMBER CHOI: No.

PANEL MEMBER PEOPLES: No.

CO-CHAIR CARROLL: No? Okay, then fine. Here is our batting order, Dale, Art, Dele and Ann and Kelly. Dale, it's yours.

PANEL MEMBER JOHNSON: Okay. Being a mode of action person myself I just want to define a little bit. And I will show you the value of it and then the difficulty of actually using it.

So number one, what are the reasons to use a common mode of action when you're looking at combinations of things? It's to see whether or not you potentially have an additive effect or a potentiative effect. So that's one of the things you look at. That's a difficult process to go through. Yo kind of figure out that you don't have an antagonism in the thing but -- so it's a difficult process but it is what you use mode of action for, many times with a combination of things together.

And then what you also use it for is to try to understand if you have a mode of action that's occurring in, let's say in an animal species. Does that same mode of action occur and is comparable in humans? And there are

several instances where it is not and I'll just say one of them. And that's thyroid cancer. You can induce thyroid cancer in rats and that same mode of action is not comparable in humans. The only thing that occurs in humans from thyroid cancer is radiation. There's a whole series of things that occur in rats. And so people use that in terms of making a judgement of whether a certain type of toxicological finding has relevance to humans. So that's one of the processes.

Now to make it even more difficult, the actual process you go through is, here's the chemical, it gets into the body, who is over there, then it's the active form of the chemical. So it's either a metabolite, it could be the parent compound, it could be a degradation product. Whatever it is, it has to get to a certain molecular target. And so it' going to interact with a molecular target. And that target has to be in the place, in the tissue, in the site where the actual toxicity is going to occur. So somehow it has to get there.

And then after that there is this repair mechanism that occur in the body and then this has to overwhelm that particular process. And then you start to go in a temporal basis from a dose and exposure standpoint at the site where this thing is occurring where it actually then translates to a tissue. You know, first it gets to a cell, affects the

cell, it goes to the tissue, affects the tissue, it could affect an organ system, and finally get to the organism.

And unfortunately what we see in terms of the toxicological end point is something that's occurring in the organism. So what you're missing is that, basically that whole mode of action. It is the single-most important thing from a toxicological evaluation but it is difficult. It's extremely difficult. And in many cases it is a speculation based on available information.

So should you use it in this context? It's hard to say. From a toxicological standpoint it's hard not to use it, you know. For anybody who has that background. But it is, it is difficult. And to hang a regulation on a mode of action is, I mean is, I would say is a very difficult situation.

Probably what you do is default to say that if there's two things that have the same toxicological end point, default to additivity and say they could be additive. That's about the only thing you could do, you know, without going any further. I think the other stuff just would take -- you'd have to do a lot of experimental stuff to actually get there.

Now when I look at the, when I look at the list of the key priority factors and so forth. What's very nice about this is that it is set up in a way that allows you to

turn it into one of Bruce's nine point diagrams. You can use it in a number of ways. You can use it in a -- you can come up with a certain type of scoring system, you can use a rank ordering system, you can put it into various diagrams. And those things can be flexible and useful for different types of compounds, different types of hazard traits, whatever you want to call them. There's different ways of looking at it. This is the way it's set up. I think it's very innovative because it's set up that allows you t do that in different ways. It lays out the bones of the process but allows you the flexibility to do it.

There will be, there will be ways of doing it that certain manufacturers will do it in a certain way. You may do it in another way, you may do it -- but, in fact, you're using the bones of the process to do it. So I think, I think I would keep it the way it is and I think it's an innovative way to do it.

CO-CHAIR CARROLL: Thank you, Dale. Julie, is your card up?

PANEL MEMBER SCHOENUNG: (Shook head).

PANEL MEMBER QUINT: Yes.

CO-CHAIR CARROLL: I'm sorry, I needed to articulate, I needed to articulate better, that's my fault. I have Art and then Dele.

PANEL MEMBER FONG: Thank you. I actually have a

clarifying question I need to ask. Is economic impact consideration part of the product prioritization process? And if it's not does it need to be? And I'm actually thinking, you know, economic impact potentially can come into play during -- and considering the exposure and chemical's factors, you know, such as potential exposure during manufacturing. The reason for that is, you know, in terms of California being the eighth-largest economy, what you do is not going to drive products away from California, I mean, that's a given. But it, perhaps, may drive development in California. So I was just wondering if economic impact considerations were part of the product prioritization process? Thank you.

CHIEF DEPUTY DIRECTOR MADRIAGO: It is not part of it as the reg is written right now, no.

PANEL MEMBER OGUNSEITAN: Well I thought that the viable -- the alternatives, economically viable was part --

CHIEF DEPUTY DIRECTOR MADRIAGO: Wait -- when manufacturers go to evaluate alternatives, yes, that is clearly one of the things that they would look at. But in terms of the Department prioritizing a chemical or product chemical combination in terms of "does it present a concern that we feel an alternatives assessment is required for." No, the regs as they're written right now don't look at economic impacts. So Art, if you or anybody else has some

suggestions that you think we need to consider, you know, by all means, please. Chair.

CO-CHAIR CARROLL: Thank you, Odette. Dele.

PANEL MEMBER OGUNSEITAN: Thank you. So in answering the question about predictability, how a manufacturer would predict the likelihood of their products being listed. I remember a brief comment this morning where we did away with "intentionally or unintentionally added chemicals of concern." And I think since six months will pass between the listing of the chemicals of concern and the priority products list, companies or manufacturers who intentionally add a chemical of concern would be on notice to check very carefully. It's not a problem that they would predict the likelihood of their product being listed as priority.

However, it's not clear to me. The manufacturers who will be surprised would be those who make products we don't intentionally add chemicals of concern. They may not know until somebody points it out. So the pathway for including that is not clear to me according to this. And we may be able to modify the prioritization criteria to clearly indicate that manufacturers are responsible for, I guess, checking their products. I don't know how else to say that. But that's a gap that I don't know how it's been addressed.

CO-CHAIR CARROLL: Thank you, Dele. Okay, so I

have Ann and Julia in the first round and then we'll go to second interventions, Kelly and Mike Wilson. Ann.

PANEL MEMBER BLAKE: Thank you. Like Ken I sort of jumped immediately to implementation as well. I think because not only am I a long-time reader of regulations but I am also a long-time implementer of regulations. So I immediately think about how this is going to work. So I'm going to try and bridge my comments that way.

I agree with many of the comments around the table that I think a narrative approach is appropriate for these regulations at this time and for allowing for flexibility and I also agree with what Dale just articulated about the way these prioritization factors are set out. A lot of flexibility.

But I think there is -- decision-making is going to come fairly rapidly upon you so it may be time to start thinking about this. And I put my card up after Julie's discussion about a decision flow because I think in the discussions around these regs you've brought a lot of decision-making, possible decision-making tools out of the woodwork and I think it may be time to start looking at those a little bit. I know I'm pushing implementation, I'm assuming that these regs will be the ones that are implemented. But something like them will involve a decision-making process.

Tim talked about decision rules that should go in there but I think something more formal should also -- you may start to look at pros and cons and limitations of decision-making models and how they impact how this plays out. And one of the things that I see missing here are -- and maybe they're in there but I didn't catch them, are criteria for regulatory response. These decision-making tools are going to lead you to those criteria for a regulatory response so it might be time to start fleshing those out a little bit.

And then I wanted to echo something that Dele brought up earlier and I didn't want this point to be lost. I think was not your intent in the language. This is a fairly small point. But on the last page of process for consideration of prioritization factors where you bring in the safer alternative thing. I think that flagged for me the same thing that it flagged for Dele. That you may consider the presence of a safer alternative but the absence of a saver alternative on the market should not halt action on the product. So I assume that that was your intent but it wasn't entirely clear and that got flagged for me.

CO-CHAIR CARROLL: Thank you, Ann. Julia.

PANEL MEMBER QUINT: Yes. I was very pleased that worker exposure was considered a prioritization factor. But I am equally concerned that it is not listed on page 4 of 7

when you talk about in (A)2, special consideration. I mean, the worker exposure, potential for exposure is not mentioned in any of the -- what is written on page 4 and 5. So I'm wondering, you know, would that send a signal to product manufacturers that, you know, that their product wouldn't be one that would be prioritized?

I'm thinking of, again, the 100 percent chemicals that are sold as consumer products that a lot of contractors just buy from, you know, hardware stores. Certainly, you know, a lot of them are solvents and very volatile so there's potential for exposure and a lot of them are widely used. So unless it's put in here it would seem to me that the Department isn't sending -- I don't get the impression that you are giving special consideration. It's included in one section but then not mentioned again. So I think that if we are serious about considering workers we should put them, they are not a sensitive sub-population but you should figure out a way to put them in.

I also wanted to comment, I think we talked about, Meg talked about aggregate exposures as opposed to effects. I think both are important because there are some chemicals that have multiple toxicities. I'm thinking of one of the regrettable substitutes, 1-Bromopropane, which is a neurotoxicant and a carcinogen, a male and female reproductive toxicant. So those would be aggregate effects

of one chemical, I think, because they are involved in a lot of different --

PANEL MEMBER SCHWARZMAN: I think in concept, yeah. I think the terms just aren't used like that, I think it's cumulative effects.

PANEL MEMBER QUINT: Right, exactly. Okay. So I thought we were going to change aggregate to --

PANEL MEMBER SCHWARZMAN: But it was the term that we talked about.

PANEL MEMBER QUINT: -- aggregate effects to aggregate exposures.

PANEL MEMBER SCHWARZMAN: Exposures, yeah. I think the term, in my experience anyway but we could follow this up.

PANEL MEMBER QUINT: Right.

PANEL MEMBER SCHWARZMAN: "Aggregate" isn't ever used with "effect."

PANEL MEMBER QUINT: Right, okay. As long as we somehow factor in those chemicals that are of concern because they have more than one toxicity. I think that's it.

CO-CHAIR CARROLL: Very good, thank you, Julia. Kelly.

PANEL MEMBER MORAN: Thanks. The hazard -- Thanks, Chair. The hazard of going very early is that then

you hear all kinds of things that you'd like to build on so I'll just, I've just got a few really quick points. And I just added one because the word "household" in the exposures really stuck out for me too because many of the water pollutants I've dealt with have been used by, for example, small businesses. So just as an example.

But the two things I really wanted to get to is that when I looked at this prioritization process the place where it fell down for me more specifically than I mentioned before was the key prioritization factors and that sequencing. That you had to get past the key prioritization factors before you got to other regulatory programs and safer alternatives, at least as I read this. That's not the case? Okay. So I'll --

CHIEF DEPUTY DIRECTOR MADRIAGO: It's actually -- let's see. On a handout on page 7 where it talks about the process for consideration of prioritization factors it kind of goes through the steps. And so actually key prioritization factors come in at the end after you've considered everything else. As you said, as an adjustment.

PANEL MEMBER MORAN: Okay.

CHIEF DEPUTY DIRECTOR MADRIAGO: So I don't know if that addresses your concern.

PANEL MEMBER MORAN: A bit. The two things I'm thinking about here is, the smaller of the two is that other

regulatory programs, some -- I think it's excellent the Department is thinking about the effectiveness of those but sometimes those programs can be very costly in their effectiveness. So there's a cost to the state or the federal government or somebody to manage something through a regulatory program, where it might be cheaper to just take the pollutant out of the product.

But more importantly is that I think that as I work through this I'm a little worried that the Department is so worried about making sure that everything it tackles is really big and hard. Or maybe not quite so hard but it's really big. And the way that most of the -- that I've seen of programs of this style work is that they attack a mix of products. So not every problem that's tacked is the biggest one in the state. That sometimes there's only a couple of products but they cause a very specific and very costly problem someplace or it's a mess at that particular location.

The best example of that I can give just out the examples I've given before is the chlorinated solvent additives to the toilets, products that are used in mobile homes. That might seem like a really small thing, it's probably only a couple of manufacturers, but golly is it expensive if you're the mobile home park that gets that stuff in your groundwater.

So just to ask you to take a look at that. I think you're getting towards that but I'm just a little worried as I go through this that there is so much focus on the biggest that perhaps that mix of things isn't quite selected for.

CHIEF DEPUTY DIRECTOR MADRIAGO: And Kelly, the only reason I laughed when you talked about the chemical additives, it's one of the oldest regulations on DTSC's books.

CO-CHAIR CARROLL: Thank you, Kelly. Mike Wilson and then I'm going to call my own number.

PANEL MEMBER WILSON: Thank you, Chair. I just have a, just a point of clarification and then a suggestion sort of based on what Kelly and Julia, Meg and Ken have said about this sentinel product idea and a decision-making tool.

The first on the point of clarification. My concern about the list, what are listed here under potential adverse impacts from chemicals of concern in the section on prioritizing products. Those are, you know, they're worth considering. They're certainly relevant scientifically.

And my concern is that -- and this gets to Ken's point that if my product is listed by the state of California as a priority product I am going to be very -- I am going to read this language very carefully and I am going to ask that has DTSC met its requirement that is stipulated

here that says you shall consider this language. How have you demonstrated cumulative effects with other chemicals of concern? Aggregate exposures, modes of action. How have you demonstrated that?

And so I would -- I just want -- I wouldn't want to be memorializing something that requires the very high standard of evidence and burden of proof if you will that we learned a lot about over the years. So giving -- I would urge you to give yourself the option and the ability to consider these factors but not to bind you to them with the requirement to document having done so.

So then the second is just a suggestion. It's sort of from this point Julie has raised around a decision-making structure, Ann as well. The Royal Commission on Environmental Pollution was charged with this same process. And they developed after a long process a system of reporting, screening, evaluation, prioritization and action.

And what they concluded was they couldn't just have priority products and nothing else. They had to have highest, high, medium, low and lowest priority. And they -- and the highest were those that were relevant to sensitive sub-population and so forth. And those were the ones they took action on.

But all of those other five categories allowed products to be binned and to send an important signal to the

market. We're not taking action on these, we're only taking action on the highest priority ones but we are concerned about these others for valid reasons, and we're going to put them in these other bins.

CO-CHAIR CARROLL: Thank you, Mike.

I wanted to go back to the question as we listed it for discussion. And in order to get into that I wanted first to look at page 29 where we have the key prioritization criteria. And it struck me in reading under the key prioritization criteria about a third to half of the way up, numbers 1, 2 and 3, that the chemicals of concern have a significant potential to cause adverse public health, environmental effects, widely distributed in commerce and significant potential for exposure.

In reading those things it struck me that those were like motive, opportunity and means. And that to go back -- if you could have motive and hazard be roughly analogous then perhaps the rest, the rest come through to you.

Now why have I dragged you through that? Well the reason is, is to go back to the question that says, what steps might be included to structure the prioritization process and so on. While under key prioritization criteria it says: "The Department shall give priority to products meeting one or more of the following criteria." I think

meeting one of those criteria is really relatively weak in the overall scheme of things.

And a signal that you could send would be to say, if you are making a product that in fact hits all three of those categories, those first three, then that's perhaps a far more significant potential impact than if it is simply widely distributed but we don't really have -- if there is a chemical of concern, a highly potent one, or for that matter we don't have much in the same way the opportunity to have adverse effect. So that's kind of the thought there is that if you were to say, and if we're -- our prejudice is in favor of products that hit all three of these criteria as being more significant and more highly likely to be priority products.

But I also want to continue to say that bullet point that we have on the page with the question that says "What steps might be included so that manufacturers are better to predict the likelihood of their products being listed as priority products?" And someone touched on this earlier. Tim, I think it was you. I actually think that's pretty good. I think it's -- the idea, the voicing of that is, we're going to be signaling what kinds of products we might be zeroing in on.

I think that's good and I want to tell you why. Because while -- Tim, I think your point was that keeping it

rather diffuse might keep more people on their toes and thinking about alternatives that they might be moving out of and that that uncertainty would be a good driver in that regard. And forgive me if I've mischaracterized your point.

PANEL MEMBER WILSON: You have.

(Laughter.)

CO-CHAIR CARROLL: I'm sorry. I'm sorry. Perhaps it was only because I was thinking of my own at the time. I think, I think in signaling, in signaling this what it suggests is, manufacturer, we have a list of chemicals of concern. You may know that you are using a chemical that is on that list. Manufacturer, we will be looking at products that fit the following criteria. When you've done that, any manufacturer who has any concern whatsoever will be saying, you now, this is starting to sound like me. And perhaps I should be doing something before we get to the point of having a specifically named chemical of concern in a product of concern.

Now you might argue that this is exactly the way you drive people to have regrettable substitutions. And I can't tell you that that won't happen but I'd be willing to make you the bet that in the greater portion of the cases you're going to wind up with people taking early action, do exactly what you want them to do, and probably in the way you want them to do it rather than, rather than what I

believe -- and this is just me, what I believe would be a minority of cases that mind wind up in what you would call a regrettable substitution. So actually I kind of like the voicing of that and signaling in that direction and encouraging people to, you know, read the tea leaves for themselves and take action before action is taken.

So I'm looking out at the group. Tim, go ahead.

PANEL MEMBER MALLOY: I had this up before you characterized what I said. The only clarification I'd make is I wasn't suggesting that that's the better way to go, to create uncertainty. In fact, I was -- I actually think predictability is a better thing. I'm just saying if your goal, depending on how you're structuring this, you might think about other ways and what it would impact.

I just wanted to respond a little bit to Ken's point because I agree with Ken, you know, so much that there are these programmatic kind of drivers of prioritization that might be important. But I'm concerned that the way these regs are written actually it would constrain a sincere effort to prioritize on the basis of those programmatic concerns. Because they are very explicit that the only thing you're really thinking about are hazard and exposure.

And I think if you think about the context in which it happens where three or four chemical product combinations come out, the question and the challenge is not

going to be whether identifying you as a product that we ought to look at is a reasonable judgment. It's going to be whether prioritizing you as opposed to all the others is a reasonable judgment.

Because the way this is written, this suggests that it is purely a judgment, of kind of a public health judgment as a matter of science as opposed to also incorporating kind of programmatic concerns and broader ideas about innovation and so on and so forth. So that's why I remain concerned that if you don't explicitly have something, some recognition in here that at least in the early segments of the program that programmatic considerations would also be relevant to prioritization, I'm worried that your subject to a challenge.

And that kind of -- Mike's point, I think, is well taken that there is language here that makes you feel like you have to consider cumulative impacts, cumulative exposure, whatever we're calling it. That you have to consider those things.

I think it's actually a good think that the regulations specifically identify a number of factors that the regulators should think about. Because look, there's plenty of examples of where regulators have failed to think about things they should have. So -- and while I wouldn't expect that to happen with the team that's working on this

at DTSC, the fact is it's an institution, not a group of people, and ten years from now there could be a totally different group of people there. The reg is supposed to be designed to apply, you know, work roughly the same no matter who the driver happens to be.

So I do think you need some of the specificity. Mike, I might disagree with you a little bit there. But I think the language could be softened a bit to not require that for every chemical you develop a whole set of data to support this -- but rather that you have essentially touched the base as you went by on each of these things and thought about whether it's relevant in this particular case and thought about it.

So I think -- But these are all kind of, you know, polishing notions. But I would say overall I think this is actually a good, a very good first cut about how to do it. I think that we have heard a lot of good comments from folks about how to, how to potentially improve it. Thank you.

CO-CHAIR CARROLL: Thank you, Tim. So looking out at the group I think I am going to officially declare you exhausted.

(Laughter.)

And suggest that we wind up what I think has been a very interesting and productive day and thank you all for your thought and interventions.

CHIEF DEPUTY DIRECTOR MADRIAGO: I do want to -- if anybody is interested, our chief scientist has volunteered. He can talk briefly about our thinking on mode of action. But as Bill says, you may all be beyond that point.

CO-CHAIR CARROLL: Having then reached the end of the --

CHIEF DEPUTY DIRECTOR MADRIAGO: Did I hear yes or no?

CO-CHAIR CARROLL: I'm sorry.

CHIEF DEPUTY DIRECTOR MADRIAGO: I'm sorry. And I don't mean to be taking over your meeting, Bill.

CO-CHAIR CARROLL: Forgive me, I'm sorry, I rolled right over it.

CHIEF DEPUTY DIRECTOR MADRIAGO: Jeff.

DR. WONG: It's not about the site of the mode of action. I mean, we included it. So if you take a look at the language it says "shall consider." So if in fact we know that there are two chemicals of concern or a family of chemicals and they all act by the same mode of action, not necessarily down to the detail that Dale talked about but they are all carcinogens, all acting -- I would say causing a heritable mutation.

And if we know that we might be able to then "shall consider," give that a higher priority or approach.

It is not that we are going to always look for information specifically about mode of action before we can take action. So that's the refinement and understanding --

PANEL MEMBER GUTH: Jeff, for the de minimis, though, it is a, you know. It's not an optional thing. I mean, it's part of the criteria for how you'd decide whether to combine chemicals in reaching the concentration.

DR. WONG: Okay, so not to make this meeting longer, I will talk to you later, Joe. A scientist and an attorney, a perfect mix.

PANEL MEMBER SCHWARZMAN: Can you just clarify, would you be redefining mode of action from what US EPA has defined it or are you just meaning you'd interpret it more loosely?

DR. WONG: I think we were interpreting it a little more loosely.

PANEL MEMBER SCHWARZMAN: Yeah, I'd be hesitant to do that.

DR. WONG: Okay, all right. I mean, thank you.

CO-CHAIR CARROLL: All right. Are we all set then? I understand there is going to be another discussion later on.

PANEL MEMBER GUTH: You'll have to talk to me later, I guess.

CO-CHAIR CARROLL: We'll have this. So that once

again brings us to the end of the day. I wanted to sort of preview tomorrow morning for you. Registration and sign-in starts at 8:00 o'clock; we will start at 8:30; we have two sessions in the morning. We have the first on Question 3 as you have it in front of you. There will also be a general discussion session now having gone through these three pieces of it. If you have over-arching considerations that you'd like to put on the table for consideration that would be the time to do that as well. Are there questions with respect to, with respect to tomorrow? Pardon me just one second.

(Off the record discussion
away from microphone.)

I'm sorry, I'm not sure whether process-wise we're calling on people in the audience or --

CHIEF DEPUTY DIRECTOR MADRIAGO: I don't think we can reopen since we -- you know, we publicly noticed when the public comment period would be and I don't think we can reopen.

CO-CHAIR CARROLL: Very good. With that I will adjourn the meeting and we will see you in the morning.

(Whereupon, the Green Ribbon Science Panel Meeting was adjourned at 4:50 p.m., to reconvene at 8:30 a.m., Tuesday, November 15, 2011.)

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CERTIFICATE OF REPORTER

I, RAMONA COTA, a Certified Electronic Reporter and Transcriber, do hereby certify that I am a disinterested person herein; that I recorded the foregoing California Department of Toxic Substances Control Green Ribbon Science Panel Meeting; that I thereafter transcribed it into typewriting.

I further certify that I am not of counsel or attorney for any of the parties to said meeting, nor in any way interested in the outcome of said matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 5th day of December, 2011.

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